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PATENT LAW: CASES & MATERIALS
~ VERSION 2.0 ~

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Introduction

I use these materials to teach a 3-credit Patent Law & Policy course. Many of the students in such a course will already have taken an IP Survey course of some kind. Although I have minimized overlapping cases with the patent-law chapter of Loren & Miller’s Intellectual Property Law: Cases & Materials (Semaphore Press), students are bound to benefit from reviewing concepts they learned in an IP Survey.

The book contains edited cases, patent figures, and excerpts, along with brief introductions to some of the subjects. The most important thing to keep in mind, however, is that this set of cases and materials is not designed as a self-contained, free-standing casebook. Rather, I have designed it for use in close conjunction with a specific softcover hornbook published by Wolters Kluwer, Janice Mueller’s Patent Law, Fourth Edition (Aspen Student Treatise Series 2013). At the start of each new topic, I have indicated which pages of Mueller’s Patent Law are most relevant to the cases I present. My thought is that others may wish to teach Patent Law in the same way, and that is why I make this set of edited cases available.

Finally, a note on my approach to editing cases: I indicate my omissions with an elipsis, and omissions present in the original with asterisks. I do not, however, indicate deletions or abridgments of citations or footnotes. Where I retain footnotes, I have tried to preserve the numbering they bear in the official case reports, but I cannot guarantee complete success on that score. In any event, one should always refer back to the official report of a case for the authoritative text.

If you decide to use this case collection to teach a course of your own—as I hope some people will—please check back to ensure that you have the most up-to-date version. This version (2.0) issued in June 2015.
Chapter 1: Invention

If you’ve been exposed to patent law before—for example, in an IP Survey course—you are, quite rightly, accustomed to thinking of the patent claim as a central feature, perhaps the central feature, of modern patent law.

But before there is a patent claim, there is an inventor who has made an invention, a working solution to a practical problem. Both the patent claim and the well-drafted written disclosure that supports the claim result from many hours of effort on the part of numerous people who come together to prepare a patent, well after an invention has already been made. The Patent Act recognizes this when it requires, in 35 U.S.C. § 112(b), that

[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The “claims” and the “invention” referenced here are different things, or this provision would make no sense. Similarly, the Patent Act’s originality requirement, embodied in—among other places—35 U.S.C. § 102(f) [‘52 Act], prohibits a person from applying for a claim where “he did not himself invent the subject matter sought to be patented[.]” This fatal derivation from another, which prevents patenting, surely precedes the drafting of any claim.

The cases below explore questions about who is, and isn’t, an inventor under the Patent Act. In so doing, they shed light on what an invention is, even before any claim is written. Keeping the reality of inventors and inventions in mind is a good way to avoid letting patent law questions descend into dysfunctional word games. As you read these cases, make note of both (a) what one must prove in order to demonstrate that one is an invention’s inventor, and (b) the types of evidence one uses to prove it.


Applegate v. Scherer
332 F.2d 571 (CCPA 1964)

Rich, Judge:

This appeal is from the decision of the Patent Office Board of Patent Interferences in favor of the junior party to interference No. 90,131, Scherer, Frensch and Stahler, who are involved on their application serial No. 714,028, filed February 10, 1958.

The senior party-appellants, Applegate and Howell (herein “Applegate”), are involved on their application serial No. 652,316, filed April 11, 1957.

† When I cite a provision that the 2011 America Invents Act (“AIA”) has superseded, I indicate that status with a shorthand “[‘52 Act],” referring to the wholesale recodification embodied in the 1952 Patent Act and the minor amendments thereto (through 2010).
The invention is defined in the following single count:

A method for controlling sea lampreys which comprises adding to a body of water inhabited by said lampreys 3-trifluoromethyl-4-nitrophenol.[†]

The Scherer application is assigned to Farbwerke Hoechst AG, of the Federal Republic of Germany, whose New York representative was Progressive Color Company. The Applegate application is assigned to the Government of the United States, represented by the Department of the Interior.

By way of background, for several decades the sea lamprey had been causing havoc in the Great Lakes to commercial and game fish. The Fish and Wildlife Service of the Department of the Interior, under the direction of Applegate and Howell, was engaged in a large-scale screening program, seeking chemical compounds which would control the sea lamprey without undue harm to desirable fish species. The scheme was to treat streams where the lamprey spawn with a chemical which would destroy the larvae.

Prior to the invention here involved, as the result of examining thousands of compounds, 3-bromo-4-nitrophenol[‡] had been found to be efficacious. This fact was disclosed in the December 17, 1955, issue of Chemical Week. Thereafter Progressive Color Company wrote a letter to the Fish and Wildlife Service on December 29, 1955 (Mr. L. C. Balling to Mr. Applegate), saying:

In various publications—specifically we refer to the December 17th issue of Chemical Week—we have observed comments on the difficulty encountered in finding a suitable chemical compound for the elimination of lampreys. We have also noted that your endeavors heretofore for an effective control of lampreys have focused on a chemical compound, viz. 3-bromo-4-nitrophenol, but because of the very high cost of this material your agency is still looking for an effective agent which perhaps could be procured at a reasonable cost.

For your guidance we would like to mention that we are the representatives of Farbwerke Hoechst A.G., Frankfurt (Main) West Germany, one of the largest chemical manufacturers in that country and have communicated with them on this subject. The Pesticide Department of Farbwerke

† [ Ed. Note — The chemical structure of this compound is as follows: ]

\[
\begin{align*}
\text{OH} \\
\text{CF}_3 \\
\text{NO}_2 \\
\end{align*}
\]

‡ [ Ed. Note — The chemical structure of this compound is as follows: ]

\[
\begin{align*}
\text{OH} \\
\text{Br} \\
\text{NO}_2 \\
\end{align*}
\]
Hoechst has advised us that the production of 3-bromo-4-nitrophenol is rather difficult and for that reason are unable to offer it to us. However, they believe that a similar chemical compound namely 3-trifluormethyl-4-nitrophenol [sic] may even be more effective for the purpose you have in mind, and in the event you are interested in this matter we would be very glad to furnish you with free samples of this material. In the affirmative please be kind enough and let us hear from you indicating at the same time what quantities you wish to receive for conducting the necessary tests.

Applegate replied to this letter on January 19, 1956, as follows:

I wish to thank you for your letter of December 29, 1955 in which you offer to provide us with a sample of 3-trifluormethyl-4-nitrophenol [sic] for testing as a candidate sea lamprey larvicide.

Due to financial limitations and personnel shortages, we have not been accepting further substances for testing. These restrictions have forced us to limit our laboratory work exclusively to tests of the several substances which have shown some promise as specific sea lamprey larvicides. However, since we are interested in exploring the structures related to 3-bromo-4-nitrophenol, and since the substance you offer is similar to this compound, we feel that it would be advantageous to work it into our program.

Only a small quantity of about three to four grams would be required for our preliminary screening tests. If you can arrange to have this amount of 3-trifluormethyl-4-nitrophenol [sic] shipped to us, we will be glad to explore its possibilities as a specific larvicide.

In February, 1956, the sample was delivered, it was tested, found to be effective, the patent applications followed, and the interference was declared.

Both parties are in agreement with the board’s view that the sole issue is originality, or, who made the invention. Scherer contends that the subject matter of the count was fully disclosed to Applegate in the letter from Progressive Color Company of December 29, 1955, by reason of which fact Applegate did not make the invention. The board so held. In support of its decision, the board pointed out that Applegate (called as a witness by Scherer, the only party taking testimony) testified that before the date of the letter he did not know of the chemical of the count. The gist of the board’s opinion is contained in the following paragraph:

There is no doubt that the Scherer et al. letter of December 29, 1955 (Exh. 3) was a conception of the invention of the count. The letter names the chemical as a substitute for the bromo-compound, which had been added to water, for the elimination of sea lampreys (Applegate et al. Exh. 6). This is all that the count requires. It is sufficient if an inventor is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation. In re Tansel, 253 F.2d 241. We conclude, therefore, that the aforementioned letter amply meets the test of conception set forth in In re Tansel, and so constitutes a full disclosure of the invention of the count in late December, 1955. This date is well prior to Applegate et al’s. record date.
In view of the disclosure to him of a complete conception of the invention of the count, the board found, as a corollary, that the reduction to practice by Applegate, by the tests which demonstrated effectiveness for the intended purpose, inured to the benefit of Scherer, citing several precedents including this court’s decision in *Shumaker v. Paulson*, 136 F.2d 700.

Applegate’s attack on the decision below is on the theory that Scherer did not conceive the invention; and to show that Scherer had no conception the further theory is propounded that under the law there could not be a conception until there was a reduction to practice, which reduction to practice was by Applegate who, therefore, was the first to conceive. Not having a conception of the invention, it is argued, Scherer could not communicate the invention to Applegate and therefore Applegate did not derive the invention from Scherer, as the board held he did. The case principally relied on to support this theory, which appears also to have been relied on heavily before the board, is *Smith v. Bousquet*, 111 F.2d 157 (CCPA 1940).

The board correctly pointed out that *Smith v. Bousquet* was not a case involving an issue of originality. Recently in *Alpert v. Slatin*, 305 F.2d 891 (CCPA 1962), we expressed agreement with views of the Board of Patent Interferences characterizing *Smith v. Bousquet* as an unusual type of case, the board saying, “In this type of research the inventor’s mind cannot formulate a completed invention until he finally performs a successful experiment.” We do not consider the instant situation to be of that type. In any event, the important distinction is that Smith and Bousquet were independent inventors pursuing their work separately, a situation which bears no parallel to the one here where one party communicated the totality of the invention defined in the count to the other, whether it be called a “conception” or by any other name.

It appears to us that appellants, as is too often the case, are relying on paragraphs lifted from a discussion of one situation to argue for a certain decision in an entirely different situation. An originality or derivation case, which this is, is quite unlike a case involving independent inventors, between whom true “priority” must be decided.1

Appellants seem to propose that there cannot be a conception of an invention of the type here involved in the absence of knowledge that the invention will work.

---

1 The board’s opinion herein twice speaks of the issue as “priority” and, of course, expresses its decision as an award of “priority” to Scherer, which is a mere formality compelled by 35 U.S.C. § 135 which treats all interferences as involving an issue of priority. It is evident, however, that in an originality case the issue is not who is the first or prior inventor, but who made the invention. Applications “interfere” when one applicant gets the invention from the other, by fair means or foul, as well as when each makes the invention independently. In awarding “priority” to the sole inventor in an originality or derivation case, it should be realized that this is merely the employment of patent law jargon which is not to be taken literally. It might be well on the next revision of the statutes to use language suited to all situations so that the board does not have to make an award of “priority” where no issue of priority exists.
Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought up by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. Such cannot be the law. A contrary intent is implicit in the statutes and in a multitude of precedents.

Thinking of the matter in this light and asking who made the invention, clearly it was Scherer who had the thought and not Applegate who merely made the test.

The decision of the board is affirmed.

**Gambro Lundia AB v. Baxter Healthcare Corp.**

110 F.3d 1573 (Fed. Cir. 1997)

**Rader, Judge:**

In this patent infringement case, Gambro Lundia AB (Gambro) appeals and Baxter Healthcare Corporation (Baxter) cross-appeals ... . The [Gambro] patent at issue, U.S. Patent No. 4,585,552 (’552 patent), claims a “system for the measurement of the difference between two fluid flows in separate ducts.” This invention recalibrates sensors during hemodialysis to accurately measure the impurities removed from a patient’s blood. Due to error in the district court’s analysis of invalidity ... this court reverses.

**Background**

Hemodialysis, commonly called dialysis, removes contaminants and excess fluid from the patient’s blood when the kidneys do not function properly. Hemodialysis works by passing a dialysate solution through a machine, called a dialyzer, which functions as an artificial kidney. In the dialyzer, the dialysate passes on one side of a porous diffusion membrane, while the patient’s blood passes on the other side. Because of the pressure differential across the membrane, blood contaminants and excess fluid diffuse through the membrane from the patient’s blood into the dialysate. These impurities diffused from the patient’s blood are known as ultrafiltrate.

After hemodialysis, the volume of the dialysate is greater. The difference between the initial and end volumes of dialysate can be used to calculate the amount of the ultrafiltrate removed from a patient’s blood. This calculation is critical to the success of hemodialysis. Removal of too much or too little ultrafiltrate may lead to severe medical problems or even death.

Repgreen Limited (Repgreen), a British bioengineering company, improved ultrafiltrate calculation. Keith Wittingham, Repgreen’s chief designer, introduced the Repgreen monitoring system, the UFM 1000, in late 1977. Wittingham’s development relied on the research of Professor Michael Sanderson. The UFM 1000 used two electromagnetic flow sensors to measure the difference between the rate of dialysate flow into and out of the dialyzer. The difference in flow rates indicated the quantity of ultrafiltrate leaving the system. To calibrate the system for an accurate measurement of dialysate flow rates, the operator would direct clean dialysate through both sensors before dialysis. This calibration method, however, could not account for clogging in the outflow sensor during dialysis. Over time, the ultrafil-
trate would build up behind the outflow sensor and disrupt the accuracy of the measurements. Experts refer to this increasing inaccuracy as “drift.”

In the late 1970s, Gambro sought to improve ultrafiltrate monitoring. During 1979, Wittingham met with Gambro engineers on two occasions to discuss Repgreen’s development of an ultrafiltrate monitor for Gambro. In July 1979, after Repgreen went bankrupt, Gambro purchased Repgreen’s hemodialysis technology, including the rights to the UFM 1000 monitor. After acquiring Repgreen’s technology, Gambro’s research team worked for three years on improving ultrafiltration monitors. In June 1982, four Gambro engineers, including Bengt-Ake Gummesson, refined the monitoring system. Their invention ultimately issued as the ’552 patent.

The Gambro invention uses valves to direct clean dialysate around the dialyzer to recalibrate the sensors during dialysis. The invention’s valve system can direct clean dialysate through the first flow sensor, around the dialyzer, and through the second flow sensor. To recalibrate, the invention momentarily blocks passage of contaminated dialysate through the outflow sensor. Instead, clean dialysate flows through the outflow sensor and recalibrates the detectors with the same clean dialysate flowing through both intake and outflow sensors. After the brief recalibration, the hemodialysis continues with contaminated dialysate flowing through the second sensor. Claim 1 of the ’552 patent reads:

[1] In dialysis equipment including a dialyser, a system for measuring the difference in the rate of flow between first and second fluid streams, said first fluid stream comprising clean dialysis solution flowing to the dialyser and said second fluid stream comprising spent dialysis solution flowing from the dialyser, said system comprising
[2] a first duct for receiving said first fluid stream flowing therethrough,
[3] a second duct for receiving said second fluid stream flowing therethrough,
[4] measuring means for measuring the difference in the rate of flow between said first and second fluid streams within said first and second ducts,
[5] and transferring means for preventing the flow of said second fluid stream through said second duct while flowing said first fluid stream through both said first and second ducts without passing said first fluid stream through the dialyser and without altering said rate of flow of said first fluid stream between said first and second ducts such that said rate of flow of said first fluid stream through said first and second ducts is substantially equal,
[6] whereby the measured difference of the rate of flow of said first fluid stream flowing through said first and second ducts is adaptable as a reference.

(Paragraph enumeration added.)

In 1984, Baxter acquired the dialysis equipment division of Extracorporeal, Inc. Dissatisfied with the accuracy of the Extracorporeal technology, Baxter developed
the Baxter SPS 550 and began marketing the device in December 1987. Gambro filed suit against Baxter ... in March 1992 claiming the Baxter SPS 550 infringed the '552 patent. In defense, Baxter asserted the invalidity ... of the '552 patent.

After a ten-day bench trial on the issues of infringement [and] validity ... the district court held claim 1 of the Gambro '552 patent invalid for ... derivation ... . The district court also entered judgment in favor of Baxter on infringement, contributory infringement, inducing infringement, and willful infringement due to the invalidity ... of the '552 patent. ...

Discussion

I. Derivation

The trial judge found that Gambro had derived the '552 invention from a Wittingham proposal left in the files when Gambro acquired Repgreen’s dialysis technology. This court reviews a finding of derivation as a question of fact. This requires acceptance of the district court’s findings unless clearly erroneous or predicated on an improper legal foundation. To show derivation, the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee. This court reviews a determination of prior conception, which must be proven by facts supported by clear and convincing evidence, as a question of law based on underlying factual findings.

Turning first to conception, the district court found that Wittingham had conceived the invention no later than July 1979. The court based this finding on Wittingham’s testimony and the Wittingham proposal left in the Repgreen file. Although the district court found Wittingham highly credible, an inventor’s testimony, standing alone, is insufficient to prove conception. Conception requires corroboration of the inventor’s testimony.

Thus, this court must weigh whether the Wittingham proposal, prepared in 1979, corroborates Wittingham’s testimony of conception. The proposal is a four-page document alluding to an ultrafiltration monitor with valves that automatically zero the sensors upon start-up. The proposal briefly discusses the Auto Zero/Start feature:

To ensure ease of operation the process of shunting the kidney in order to zero monitor will be done automatically on pressing of the start button. This will also initiate the automatic zeroing of unit.

Baxter contends that this document also discloses the concept of recalibration (or zeroing) during dialysis. In support of this contention, Baxter identifies the following passage from the proposal:

A zero button may also be necessary in order to zero Ultrafiltration Monitor but not start the automatic control (start signal cannot be allowed till 20 minutes after switch on?).

Baxter argues that the only reason to zero the monitor without starting the automatic control is to zero the monitor when it is already started—in other words, during dialysis.
Baxter’s novel interpretation of this single ambiguous passage in the Wittingham proposal, however, lacks sufficient support to corroborate Wittingham’s conception testimony. First, the reference is so unclear that even Wittingham conceded that this single sentence does not state expressly the concept of recalibration during dialysis. In fact, the parenthetical within the sentence suggests that the device should not be in use “till 20 minutes after switch on.” For this reason, among others, Professor Sanderson, an expert in dialysis whose early research formed the basis of Wittingham’s work, testified that one of ordinary skill in dialysis in 1982 would not have understood this obscure passage to disclose recalibration during dialysis. Professor Sanderson noted that the Repgreen monitor needed twenty minutes to stabilize before use. Therefore, this obscure sentence more reasonably suggests the use of the zero button during the pre-dialysis warm-up period.

In addition, the obscure sentence states that depressing the button calibrates the monitor, but does “not start the automatic control.” In its ordinary start-up operation, the Repgreen monitor would calibrate the monitor, start the automatic control, and finally automatically begin the dialysis. The reference to “zeroing” before the automatic control phase thus suggests calibration before dialysis, not during dialysis. Further, if Wittingham had conceived of recalibration during dialysis—an important advance in the dialysis art—the four-page Wittingham proposal would surely contain more than a single cryptic sentence memorializing the advance. Accordingly, this court determines that the Wittingham proposal does not corroborate conception.

The only other evidence offered by Baxter to corroborate conception is the testimony of Mr. Smith, Wittingham’s supervisor at Repgreen. Referring to the ambiguous sentence, Smith testified that the Wittingham proposal included the idea of calibration during dialysis. The trial judge, however, did not rely on this self-serving testimony in finding prior conception. Moreover, as noted above, the language of the Wittingham proposal itself belies Smith’s testimony about calibration during dialysis. In sum, this court concludes that Baxter failed to meet its burden of proving by facts supported by clear and convincing evidence that Wittingham conceived the invention of the ’552 patent.

The second prong of the derivation test—communication of the prior conception to the named inventor—poses similar difficulties for Baxter. As an initial matter, the district court applied the wrong legal standard. Citing New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878 (Fed. Cir. 1992), the district court concluded that Baxter did not need to prove communication of the entire conception, but rather only so much of the invention “as would have made it obvious to one of ordinary skill in the art.” Gambro Lundia AB v. Baxter Healthcare Corp., 896 F. Supp. 1522, 1540 (D. Colo. 1995) (citing New England Braiding, 970 F.2d at 883). Based on this reasoning, the district court applied the obviousness standard in 35 U.S.C. § 103 to determine that the named inventors received enough information to make the invention obvious to one skilled in the dialysis art. This reasoning, however, misconstrues the dictum in New England Braiding and introduces incorrectly an obviousness analysis into the test for derivation.
The Supreme Court announced the standard for finding communication of a prior conception over 125 years ago in *Agawam Woolen v. Jordan*, 74 U.S. 583 (1868). The Court required a showing that the communication “enabled an ordinary mechanic, without the exercise of any ingenuity and special skill on his part, to construct and put the improvement in successful operation.” Id. (emphasis added). This court’s predecessor consistently applied this Supreme Court standard. See, e.g., *Hedgewick v. Akers*, 497 F.2d 905, 908 (CCPA 1974) (“Communication of a complete conception must be sufficient to enable one of ordinary skill in the art to construct and successfully operate the invention.”) (emphasis added).

This court recognizes that the district court’s incorrect derivation standard springs from dictum in this court’s *New England Braiding* decision. In that case, this court noted: “To invalidate a patent for derivation of invention, a party must demonstrate that the named inventor in the patent acquired knowledge of the claimed invention from another, or at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art.” *New England Braiding*, 970 F.2d at 883. This dictum did not in fact incorporate a determination of obviousness into a § 102(f) analysis. Indeed, this court in *New England Braiding* did not apply such a test.

The *New England Braiding* court upheld the denial of a preliminary injunction because the record showed a likelihood that New England Braiding’s patent was invalid under 35 U.S.C. § 102(f). The record showed that George Champlin, the named inventor, worked for the A.W. Chesterton Co. and participated in experiments that developed the invention. One Chesterton employee testified that Champlin had said, when he left to start his own company, that he wanted to patent the experimental braiding if Chesterton decided not to do so. Champlin denied these allegations. Id. at 883-84. The key issue was a credibility determination between the witnesses for the two parties. The sufficiency of the communication, particularly whether the invention was obvious in light of such disclosure, was not at issue. Thus, *New England Braiding* did not incorporate an obviousness test into the § 102(f) analysis.

Applying the correct standard—whether the communication enabled one of ordinary skill in the art to make the patented invention—this court discerns insufficient evidence of communication. Wittingham testified that he was not sure that he had discussed calibration during dialysis with anyone at Gambro, and he did not discuss the sensor contamination problem. The trial judge based his finding of communication solely on Wittingham’s written proposal. Gambro acquired this document when it acquired Repgreen’s technology. During discovery, the proposal appeared in the files of one of the named inventors. However, as discussed above, the proposal does not disclose recalibration during dialysis to one skilled in the art at the relevant time. If the proposal does not disclose recalibration during dialysis, it cannot serve as the basis for a communication of that idea. Thus, under the correct legal standard, the record evidence is insufficient to support a finding of communication. The district court erred in finding communication and conception, and, hence, the finding of derivation is also clearly erroneous.

...
Lourie, Judge:

Thomas A. Wilkins appeals from [a] decision ... entering declaratory judgment in favor of General Electric Company and GE Wind Energy, LLC that Wilkins is not a co-inventor of GE’s U.S. Patent 6,921,985 pursuant to 35 U.S.C. § 256. Because Wilkins failed to prove by clear and convincing evidence that he was entitled to co-inventorship of the ‘985 patent, we affirm.

Background

Wind turbines convert wind into electrical energy that is supplied to the power grid. Random events such as lightning strikes and animal contacts can cause wires of the power grid to short, resulting in a reduction in the amount of voltage on the power grid. Such “low voltage events” can damage nearby wind turbines, either by causing the blades of a turbine to rotate out of control or by causing electric current to back up into the generator rotor of a turbine. Conventionally, wind turbines protected against those harms by disconnecting from the power grid during a low voltage event. However, as wind began providing a greater percentage of the overall grid power, utilities began to require that wind turbines remain connected to the grid and continue to operate during a low voltage event. The ability of wind turbines to meet that requirement is known as “low voltage ride through” (“LVRT”).

GE’s ‘985 patent names five co-inventors who were each members of a team of GE engineers based in Salzbergen, Germany that was tasked with meeting the standard of a German utility company, which required wind turbines to ride through voltage drops down to 15% of nominal voltage.

The ‘985 patent is directed to controlling key components of a wind turbine that would allow it to remain connected to the power grid and to safely ride through a low voltage event. ‘985 patent, col. 2, ll. 24-34. The LVRT solution described in the ‘985 patent involves: (i) a blade pitch controller that varies the angles of the wind turbine blades to maintain safe rotation speeds; (ii) a converter controller that “guard[s] against excessive currents in the inverters” by selectively activating and deactivating a circuit to shunt excess current away from the turbine’s sensitive components; and (iii) a turbine controller that provides overall control of the turbine and shuts down nonessential components during a low voltage event.

The independent claims of the ‘985 patent reflect those specific controller functions. Claims 1 and 15 are representative and read as follows:

1. A wind turbine generator comprising: a blade pitch control system to vary a pitch of one or more blades; a turbine controller coupled with the blade pitch control system; a first power source coupled with the turbine controller and with the blade pitch control system to provide power during a first mode of operation; and an uninterruptible power supply coupled to the turbine controller and with the blade pitch control system to provide power during a low voltage event; wherein the turbine controller causes the blade pitch control system to vary the pitch of the one or more blades in re-
response to the transition in response to detection of a transition from the first mode of operation.

15. A wind turbine generator comprising: a generator; a power converter coupled with the generator, the power converter having an inverter coupled to receive power from the generator, a converter controller coupled with the inverter to monitor a current flow in the inverter wherein the converter controller is coupled to receive power from an uninterruptible power supply during a low voltage event, and a circuit coupled with the input of the inverter and with the converter controller to shunt current from the inverter and generator rotor in response to a control signal from the converter controller.

Col. 6, l. 65 – col. 7, l. 13; col. 7, l. 58 – col. 8, l. 3 (emphases added). Each claim requires an uninterruptible power supply ("UPS"), which powers the various controllers so that they can perform their functions during a low voltage event. Wilkins is not named as a co-inventor of the '985 patent.

Wilkins began working for GE’s predecessor company Enron Wind Corporation, doing business as Zond Wind Energy Systems ("Enron"), in 1998. In the course of that employment, Wilkins was involved in adapting wind turbines to meet certain LVRT requirements at an Enron-owned wind farm in Minnesota known as Lake Benton II. After modification, the Lake Benton II wind turbines were capable of riding through voltage drops down to 70% of nominal voltage. Although those turbines incorporated a small capacitor that briefly powered one sensor during a grid outage, that capacitor did not power the converter controller during a low voltage event, nor did modification of the Lake Benton II wind turbines contemplate blade pitch control or a circuit that shunted excess current away from the generator rotor and inverter in order to achieve LVRT. After GE acquired certain assets from Enron, Wilkins worked as an engineer at a GE wind turbine facility in Tehachapi, California.

It is undisputed that the German team had developed detailed specifications and concept documents of its LVRT solution by July 2002 and was planning a presentation to review the technical details, including the use of controllers powered by a UPS, which were available for download through an internal GE website.

Correspondence between Wilkins and two of the named inventors in spring and summer of 2002 indicates that the German team was consulting Wilkins for confirmation that their invention, which was then implemented on German wind turbines, would work with the different “60 Hz” grid requirements and turbine components used in the United States. In particular, the correspondence revealed that the work done at Lake Benton II was not interchangeable with the specifications and requirements of the German LVRT design, and no mention was made of a UPS coupled to a converter for the purpose of LVRT. Wilkins traveled to Germany in August 2002. Although Wilkins admitted that no documents exist for that trip, he alleged that he shared his ideas from Lake Benton II and conveyed specific elements of the '985 patent to the German team at that time.

In October 2002, Wilkins and a team of GE engineers in California were tasked with developing an LVRT solution for the utility company Florida Power and Light. In the course of that work, Wilkins prepared a document entitled “Design and Cost
Analysis,” in which he summarized several ideas, along with a proposal to use a UPS. The figures depicted in that Design and Cost Analysis “reflect *** [w]here to place the UPS in the circuit” and show that the UPS was proposed to insulate the wind turbine from the power grid during a low voltage event by placing the UPS between the power grid and the turbine. In that arrangement, the turbine controller and converter controller would be situated between the grid and the UPS, and therefore could only receive power from the grid during a low voltage event and not from the UPS. Wilkins admitted that the Design and Cost Analysis does not show the UPS powering the wind turbine’s blade pitch controller, and that, although the document does discuss a shunting circuit, it is not the selectively activating and de-activating circuit of the ’985 patent. Wilkins left GE later in 2002.

The ’985 patent is one of several asserted by GE against Mitsubishi Heavy Industries, Ltd. and Mitsubishi Power Systems Americas, Inc. in at least two lawsuits, including a patent infringement case in ... Texas and an investigation before the United States International Trade Commission (“ITC”). The ’985 patent is also one of the patents at issue in an antitrust suit that Mitsubishi brought against GE in ... Arkansas.

In the ITC proceeding, Mitsubishi challenged the validity of the ’985 patent and hired Wilkins to search for relevant prior art. Wilkins worked approximately 1,000 hours[†] in an effort to invalidate the ’985 patent, for which he received approximately $200,000. Mitsubishi also argued that the ’985 patent was unenforceable based on a claim that GE intentionally failed to name Wilkins as a coinventor. The [ITC] administrative law judge rejected that argument, concluding that Wilkins had co-invented the ’985 patent but finding that GE did not intend to deceive the [PTO] by failing to name Wilkins as a co-inventor. The ITC did not review the ALJ’s finding that there was no inequitable conduct, and Mitsubishi did not challenge that determination on appeal to this court.

Following the ITC proceedings, Wilkins averred that he retained ownership rights in the ’985 patent and U.S. Patent 6,924,565, which is directed to continuous reactive power support for wind turbine generators that GE prosecuted in Wilkins’s name after he left the company. Wilkins subsequently entered into another set of agreements with Mitsubishi under which Mitsubishi paid him $100,000 for an option to license the ’985 patent and an additional $200,000 for “consulting” work. In return, Wilkins agreed to “take all necessary and reasonable steps” to support Mitsubishi in actions against GE regarding the ’985 patent.

In due course, Mitsubishi exercised its option, and during licensing negotiations Wilkins’s counsel demanded significant additional funds for Wilkins to “stay in the game” against GE, making clear that Mitsubishi’s offer of $200,000 was “inadequate for Wilkins to keep his place at the table.” Wilkins’s counsel promised that Mitsubishi would have “every ability to coordinate and manage Wilkins’ involvement to maximize [Mitsubishi]’s position in the litigation” if it agreed to pay more. Mitsubishi consequently paid Wilkins a nonrefundable licensing fee of $1.5 million

† [ Ed. Note — At 40 hrs/wk, it takes 25 weeks, or about six months, to work 1,000 hours. ]

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and retained an option to extend that license upon payment of an additional $1 million.

GE subsequently filed suit in … California seeking to quiet title to the ’985 and ’565 patents. Wilkins counterclaimed, seeking (i) to be added as a named inventor of the ’985 patent under 35 U.S.C. § 256 and (ii) a declaration that he has an ownership interest in the ’985 and ’565 patents. Mitsubishi intervened and also filed counterclaims seeking a declaration that Wilkins is a coinventor and co-owner of the ’985 patent.

The district court initially found that GE was likely to prevail on its claims and preliminarily enjoined Wilkins from licensing either of the patents in suit. After subsequently refusing four times to take an unqualified oath to tell the truth at his deposition, behavior that the court deemed “not acceptable,” Wilkins filed a declaration calling the district court “obtuse,” “overly assumptive,” and “ignorant.” The district court eventually dismissed GE’s ownership claims on summary judgment as time-barred by the statute of limitations. The court then conducted a bench trial on Wilkins’s and Mitsubishi’s inventorship counterclaims and held that they had failed to establish that Wilkins co-invented the subject matter of any claim of the ’985 patent.

In reaching that conclusion, the district court determined that Wilkins had undermined his own credibility. The court noted that Wilkins had received approximately $2 million from Mitsubishi by the time of the trial and pointed to the documentary evidence showing that Wilkins had indeed demanded those substantial payments in order for him to “stay in the game” so that Mitsubishi could “manage” him. The court thus concluded that Wilkins was “biased,” “a purchased witness/party,” and “more concerned about gaining personal advantage than testifying truthfully.” The court found that Wilkins lacked credibility based on his “purposefully evasive” responses to even basic questions, noting that Wilkins was “repeatedly impeached during cross-examination, to the point where the veracity of even simple answers w[as] called into question.” The district court judge described Wilkins as “one of the worst witnesses I have ever seen.”

The district court analyzed all of the evidence presented, including: documents from Wilkins’s work at Lake Benton II, upon which Wilkins had based his primary inventorship theory; testimony from the German engineers and Wilkins’s correspondence with them regarding his 2002 work and trip; Wilkins’s Design and Cost Analysis; and GE’s prosecution of the ’985 patent. Based on its credibility determination, factual findings, and review of the entire record, the court concluded that Wilkins and Mitsubishi had not carried their burden to prove inventorship by clear and convincing evidence because, “[s]imply put, there [we]re no reliable documents that verify what, if anything, Mr. Wilkins contributed to any of the claims of the ’985 patent.”

Mitsubishi and Wilkins timely appealed. GE cross-appealed from the summary judgment orders holding that its quiet title claims were time-barred. By voluntary dismissal, the appeal was terminated as to Mitsubishi, as was GE’s cross-appeal. The record indicates that Wilkins subsequently filed related suits … asserting claims for malicious prosecution and abuse of process against GE and its counsel in the district
court action that is the subject of this appeal, seeking $1.5 billion in damages from GE and its counsel based upon their assertion of breach of contract claims against Wilkins in the district court. The district court in the instant case denied Wilkins’s motion for sanctions premised on the same arguments underlying those new complaints, but Wilkins did not appeal that determination. …

Discussion

Inventorship is a question of law, which we review without deference. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). We review the district court’s underlying findings of fact for clear error. *Id.* Because the issuance of a patent creates a presumption that the named inventors are the true and only inventors, *id.*, the burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence, *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 980 (Fed. Cir. 1997). Credibility determinations are entitled to strong deference. See *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 929 (Fed. Cir. 2012); *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1330 (Fed. Cir. 1998).

Although Wilkins admits that his credibility was impeached, he asserts that those instances of impeachment only extended to immaterial and tangential points and notes that the ALJ did not criticize Wilkins’s credibility in the previous ITC action. Wilkins argues that the district court erred in concluding that he is not a co-inventor of GE’s ’985 patent because the court did not compare the conception described in Wilkins’s Design and Cost Analysis document to the claims. Wilkins further contends that the Design and Cost Analysis is among the corroborating evidence that the court did not analyze as a whole under the rule of reason standard. Wilkins maintains that he is an inventor because that conception document meets every limitation of the independent claims; he asserts that he conceived of using a UPS as claimed for LVRT and that the claims of the ’985 patent do not limit the location of the UPS.

GE responds that Wilkins’s impeachment went to core issues including the work that he supposedly did and the interactions that he supposedly had with the named inventors. GE contends that the district court correctly applied the rule of reason standard, but that Wilkins did not first provide any credible testimony for the court to corroborate.

We agree with both GE and the district court that, in light of all the record evidence, Wilkins did not prove his inventorship claim by clear and convincing evidence because he did not present any credible testimony that could be corroborated. In order to guard “against courts being deceived by inventors who may be tempted to mischaracterize the events of the past through their testimony,” the law requires corroboration of a putative inventor’s credible testimony, the sufficiency of which is measured under a “rule of reason” standard. *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1374 (Fed. Cir. 2009). Therefore, as a threshold matter, in order for the rule of reason requirement to even apply there must be some evidence that a fact-finder can find reasonable; the putative inventor must first provide credible testimony that only then must be corroborated. See, e.g., *Univ. of Colo. Found. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1308-09 (Fed. Cir. 2003) (rejecting inventor-
ship theory based upon putative inventor’s discredited testimony). The very purpose of the rule of reason requirement is to verify the credibility of a putative inventor’s story. *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1364 (Fed. Cir. 2001); *Ethicon*, 135 F.3d at 1461; *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993) (“An evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor’s story may be reached.”).

The district court found that Wilkins was biased, based in part on his financial relationship with Mitsubishi. The court’s determination is supported by documentary evidence showing that Wilkins demanded and received substantial payments in order for him to “stay in the game” so that Mitsubishi could “manage” him. The court also found that Wilkins further undermined his own credibility while testifying at trial because his responses to even basic questions were “purposefully evasive” and he was “repeatedly impeached during cross-examination, to the point where the veracity of even simple answers was called into question.” Based on the trial record, we find no clear error in the district court’s assessment that the substance of Wilkins’s testimony, which addressed central issues such as conception and contribution, was inconsistent and purposefully evasive. We agree with the district court’s conclusion that Wilkins left his case with no credibility.

Although Wilkins is correct that the ALJ did not criticize Wilkins’s credibility in the previous ITC action, that ITC decision was made without the benefit of the complete factual record, including the relationship between Wilkins and Mitsubishi, and without observing the shifting and inconsistent testimony that he repeatedly provided at the district court trial. The ALJ’s findings, made only in the context of an inequitable conduct analysis, are insufficient to overcome the district court’s credibility determinations in this proceeding concerning correction of inventorship.

Accordingly, without credible testimony from Wilkins, there was nothing to corroborate. And although there was no need for the district court to assess any corroborating evidence, the court nevertheless carefully and thoroughly analyzed all of the evidence presented under the rule of reason standard and concluded that it did not contain clear and convincing evidence showing that Wilkins made any inventive contribution to the claims of the ’985 patent. The district court expressly assessed witness testimony and dozens of supposedly corroborating documents, including Wilkins’s Lake Benton II documents, the 2002 correspondence between Wilkins and the named German inventors, Wilkins’s October 2002 Design and Cost Analysis, and documents from GE’s prosecution of the ’985 patent. We see no error in the district court’s analysis of that evidence.

Moreover, we find no merit in Wilkins’s suggestion that the district court should be faulted because its opinion does not specifically address every admitted trial exhibit. A district court need not write an opinion that expressly discusses every admitted exhibit. *See Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 906 (Fed. Cir. 1986) (recognizing that a district court need not provide a “complete discussion of all possible permutations and combinations” of the evidence because we “presume that a fact finder reviews all evidence presented unless he explicitly expresses otherwise”). But even so, the district court’s opinion in this case makes clear that it did take all of the admitted evidence into account in reaching its decision. The court
concluded “that the heavy burden of proof by clear and convincing evidence has not been met, and therefore that Mr. Wilkins should not be named a coinventor of the ’985 patent” after “[h]aving considered the evidence presented at trial and the parties’ proposed findings of fact and conclusions of law submitted after trial.”

Similarly, the district court did not err simply because, after cataloging the many problems with each piece of purportedly corroborating evidence proffered by Wilkins, it did not expressly dismiss that same evidence for the second time “as a whole.” See, e.g., Symantec Corp. v. Computer Assocs. Int’l, 522 F.3d 1279, 1295-96 (Fed. Cir. 2008) (rejecting inventorship claim after individually addressing flaws with each piece of corroborating evidence); Woodland Trust v. Flowertree Nursery, 148 F.3d 1368, 1373 (Fed. Cir. 1998) (noting that the district court appropriately excluded evidence “lacking detail and clarity” from its rule of reason analysis). The district court considered the entire record and found that it did not support Wilkins’s inventorship claim. Wilkins does not argue that any of those factual findings were clearly erroneous, and we likewise identify no clear error. Wilkins’s argument depends on a selective reading of the record, which ignores facts that are unhelpful to his case and is in itself contrary to a proper rule of reason analysis.

Although Wilkins appears to have relied on his work at Lake Benton II when advocating his inventorship theory before the tribunals below, he suggests now that the October 2002 Design and Cost Analysis that he prepared for Florida Power and Light clearly and convincingly demonstrates his contribution to the German team’s LVRT solution and the claims of the ’985 patent, viz., use of a UPS. Notwithstanding that the record is devoid of proof that the German engineers relied on anything discussed in that document as part of their conception and that Wilkins provided no credible testimony for that document to corroborate, our review of the record verifies that the district court did not clearly err in finding that the document does not disclose any of the subject matter claimed in the ’985 patent.

Record evidence confirms that Wilkins collected ideas from many different collaborating GE sources when preparing the Design and Cost Analysis. Wilkins himself conceded that the idea to use a UPS to perform LVRT was not novel in 2002. Accordingly, if all Wilkins allegedly contributed to the ’985 patent was the idea to use a UPS, then he would have contributed nothing beyond what was already known in the art. That is not sufficient to name Wilkins as a co-inventor. Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997) (“[A] person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are well known and the current state of the art.”). As the district court noted, Wilkins did not invent or contribute to the use of the circuit recited in claim 15 of the ’985 patent to protect the converter by shunting current away from the sensitive components of the wind turbine system. And the prosecution history of the ’985 patent shows that it was the combination of a UPS and such a circuit that allowed GE to overcome a prior art rejection in getting its claims allowed.

Moreover, on its face, the Design and Cost Analysis does not even depict the key feature Wilkins claims to have invented, i.e., a UPS powering the wind turbine’s three controllers. As discussed above, the plain language of the ’985 patent claims requires the UPS to be “coupled to” the requisite controllers to provide power dur-
ing a low voltage event. But the figures in Wilkins’s Design and Cost Analysis depict the turbine controller and converter controller situated between the power grid and the UPS so that they could only receive power from the grid during a low voltage event and not from the UPS, which is depicted as situated to insulate the other components of the wind turbine from the grid. Furthermore, Wilkins admitted that his Design and Cost Analysis does not show the UPS powering the wind turbine’s blade pitch controller. The district court thus did not clearly err in concluding that the Design and Cost Analysis did not recite the UPS limitations claimed in the ’985 patent.

A co-inventor “must contribute in some significant manner to the conception or reduction to practice of the invention [and] make contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention.” Nartron Corp. v. Schukra U.S.A., Inc., 558 F.3d 1352, 1356-57 (Fed. Cir. 2009). Wilkins’s evidence is bereft of any such proof. The undisputed record confirms that the German inventors had already conceived of their controller-based LVRT solution before corresponding with Wilkins to discuss American grid requirements or meeting with Wilkins in Germany. See Symantec, 522 F.3d at 1296 (holding that evidence of discussions between named inventor and putative co-inventor concerning subject matter of claimed invention was insufficient to establish co-inventorship).

Conclusion

For the foregoing reasons, we conclude that the district court did not err in determining that the heavy burden of proof by clear and convincing evidence was not met, and therefore that Wilkins should not be named a coinventor of the ’985 patent. The judgment of the district court is therefore affirmed.
Chapter 2: Claims

The patent claim establishes the boundaries of the patentee’s right to exclude others. It is thus a central mechanism of patent law. This chapter proceeds in three steps. First, it specifies the portion of Mueller’s Patent Law that describes the claim mechanism in detail. Second, it turns to the techniques for construing disputed claim terms. Third, it explores a validity doctrine that is intertwined with the claim construction process—namely, claim definiteness.

The Claim Mechanism

Mueller’s Patent Law: 77-80, 90-100, 114-115, 446-449

Blocking Patents

Al invents the knife, and obtains a patent on it. Barb later invents the switchblade, and obtains a patent on it. Al’s sole patent claim is the one on the left, and Barb’s sole patent claim is the one on the right.

<table>
<thead>
<tr>
<th>Al’s knife claim</th>
<th>Barb’s switchblade claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>A knife comprising: a handle; and a blade, said blade having at least one sharpened edge, and said blade being affixed at one end of said blade to one end of said handle.</td>
<td>A knife comprising: a handle; a blade, said blade having one sharpened edge, and said blade being movably affixed at one end of said blade to one end of said handle; and means for locking said blade in an open position or in a closed position</td>
</tr>
</tbody>
</table>

Can Barb make switchblades without Al’s permission, or would it infringe Al’s claim for her to do so? What about Al … can he make switchblades without Barb’s permission, or would it infringe Barb’s claim for Al to do so? If neither can enter the lucrative switchblade market without Al’s say-so, and the switchblade market wouldn’t even exist were it not for Barb’s inventive skill, should they find a way to share the gains of supplying that market?

Claim Construction


The first claim construction case relates to a humble concern—namely, the slipperiness of socks. First read the patent in dispute, then read the decision.
Miller's Patent Cases

(12) United States Patent
Boersema

(10) Patent No.: US 6,385,779 B2
(45) Date of Patent: May 14, 2002

(54) INFANT SOCK

(76) Inventor: Tasha Boersema, 683 Sleepy Hollow
La., Holland, MI (US) 49423

( *) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/894,736
(22) Filed: Jun. 28, 2001

Related U.S. Application Data

(60) Provisional application No. 60/214,377, filed on Jun. 28,
2000.

(51) Int. Cl.7 ................................................. A41B 11/00
(52) U.S. Cl. .............................................. 2/239; 2/409; 36/9 R;
36/10

(58) Field of Search ..................................... 2/239, 409, 80,
2/83; 36/110–113, 136, 7.1 R, 72, 9 R,
9 A, 10, 70 R, 4

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Primary Examiner—Gloria M. Hale
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Todd, LLC

ABSTRACT

An infant sock for crawling infants includes a generally
rubber sock member having an upper surface, a lower
surface, a toe surface forming a closed end, and an open end.
An elastic band is attached at the open end receiving an
infant’s foot. A gripper member covers at least a portion of
the upper surface, the lower surface and the toe surface and
has an increased coefficient of friction.

13 Claims, 2 Drawing Sheets
1 INFANT SOCK

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. provisional patent application Ser. No. 60/214,377 filed Jun. 28, 2000.

BACKGROUND OF THE INVENTION

The present invention relates generally to a sock for an infant and, in particular, to a sock designed to provide additional traction for a crawling infant.

Dressing an infant with fabric socks is advantageous in many ways. Socks are aesthetically pleasing, keep the infant’s feet warm and protect the infant’s feet from minor cuts and abrasions. When the infant becomes ambulatory, however, socks can be disadvantageous on smooth floor surfaces, such as hardwood or linoleum floors, because there is a very low coefficient of friction between fabric material of the socks and the floor surface. This poses an increased risk of injury because the infant may slip and fall on the smooth surface while wearing only the fabric socks. Dressing the infant with shoes is one solution to this problem, but it is not always desirable, and is often difficult, to put shoes on an ambulatory infant.

This is a recognized problem, and many prior art infants socks, therefore, have been fitted with material that provides greater traction on the bottom of the sock. This material is also referred to as a gripper area. These prior art socks have worked well for those infants who have already progressed to walking, because the portion of the sock with the gripper area is in contact with the smooth floor surface. These prior art socks, however, have been disadvantageous for crawling infants, because typically the feet of crawling infants contact the floor surface with portion of the foot closest to the toes or the top of the foot, rather than the bottom of the foot. Because the top portion of the prior art socks did not contain a gripper area on the toes or top of the sock, the same problems were encountered as with socks without any gripper area, which results in an increased risk of injury to crawling infants wearing the prior art socks.

It is desirable to provide an infant sock that will provide greater traction for crawling infants as well as for infants that are already walking.

It is an object of this invention, therefore, to provide an infant sock suitable for both crawling and walking infants with a decreased risk of injury to the crawling infant wearing the sock.

SUMMARY OF THE INVENTION

The present invention concerns an infant sock for use with a crawling infant. The infant sock includes a tubular sock member with an upper surface, a lower surface, and a toe portion connecting and enclosing the upper and lower surfaces at a leading edge of the sock member. At the opposite end of the tubular sock member, the upper surface and lower surface form an open end for receiving a foot. A gripper area is attached to the exterior portion of the sock member and preferably extends from the upper surface to the toe area and further to the lower surface. The gripper area is preferably a single piece of frictional material that covers an area along the lower surface, and a lesser area on the upper surface. The gripper is preferably attached to the fabric of the sock member by a thermal process. The sock member preferably includes an elastic member at the open end to keep the sock in place on the infant’s foot and lower leg.

Alternatively, the sock member is advantageously foot-shaped for ease of dressing the infant.

Alternatively, the gripper area is formed in a tread pattern and can include transversely or circumferentially spaced ribs along the upper surface, toe portion, and lower surface.

The present invention recognizes that prior art socks were suitable neither for providing traction to crawling infants nor for reducing the risk of injury to crawling infants on smooth floor surfaces. With a gripper area at the top surface and toe portion of the sock member, the present invention provides infants wearing the present invention a greater ability to crawl on smooth surfaces, while reducing the risk of injury to crawling infants. The present invention is also suitable for infants who have progressed to walking, because the gripper area extends to the lower surface of the sock member.

The present invention is a novel improvement over the prior art because while the prior art teaches many different varieties of infant socks, none of the prior art teaches an infant sock with a gripper area extending to the toe and the upper surface of the sock member for the purpose of providing traction to crawling infants.

DESCRIPTION OF THE DRAWINGS

The above, as well as other advantages of the present invention, will become readily apparent to those skilled in the art from the following detailed description of a preferred embodiment when considered in the light of the accompanying drawings in which:

FIG. 1 is a bottom view of an infant sock in accordance with the present invention;

FIG. 2 is a side view of the infant sock in FIG. 1; and

FIG. 3 is a perspective view of an alternative embodiment of an infant sock in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIGS. 1 and 2, an infant sock is shown generally at 10. The infant sock 10 includes a generally tubular sock member 11. The sock member 11 includes an upper surface 18, a lower surface 16, and a toe surface 14 on the exterior thereof. The toe surface 14 defines an enclosed end of the sock member 11 opposite an open end for receiving an infant’s foot (not shown). The sock member 11 is preferably constructed of a natural fabric material, such as cotton, or a synthetic fabric material, such as Lycra or spandex, or a combination of such materials. Preferably the infant sock 10 is latex free. The upper surface 18 and the lower surface 16 preferably consist of the same amount of fabric material so as to ensure a good fit on an infant’s foot (not shown.) The infant sock 10 is preferably sized to fit an infant learning to crawl. A typical age for such an infant is about four months of age to about one year of age.

A gripper member 12 is adhered to the lower surface 16, the upper surface 18, and the toe surface 14. Preferably the gripper member 12 covers a continuous area of the sock member 11 extending from a seam on the upper surface 18 (not shown) at the toe surface 14 to a front-to-back section of the lower surface 16 of the sock member 11. The area covered by the gripper member 12 on the lower surface 16 is preferably greater than the area covered by the gripper member 12 on the upper surface 18. The gripper member 12 preferably covers most of the area of the toe surface 14.

Alternatively, the gripper member 12 covers a greater area on the upper surface 18 than on the lower surface 16. The gripper member 12 is preferably constructed of a material
that increases the coefficient of friction with a floor surface, such as a rubberized material or the like, having a coefficient of friction greater than a coefficient of friction of the material from which the sock member 11 is made. The material of the gripper member 12 is flexible and withstands laundering. The material of the gripper member 12 may be adhered to the sock member 11 by a thermal process, such as an applique process.

The sock member 11 also includes an annular elastic band 22 attached to the upper surface 18 and lower surface 16 that forms the open end for receiving the infant's foot. The elastic band 22 also aids in keeping the sock member 11 in place on the infant's lower leg (not shown). The elastic band 22 preferably includes a fabric sheath for comfort. A tubular entrance band 24 is attached to the elastic band 22. The entrance band 24 is preferably constructed of the same material as the sock member 11 and may include a typical knitting pattern 26. The knitting pattern 26 preferably consists of multiple parallel ribs of knitted fabric that may be folded towards the toe surface 14 as desired for aesthetic purposes. The sock member 11 also includes an emblem or similar indicia 20 on the lower surface 16. The emblem 20 may be constructed of the same material as the gripper member 12. Alternatively, the emblem 20 is attached to the upper surface 18 or to the entrance band 24.

Referring now to FIG. 3, an alternative embodiment of an infant sock is shown generally at 100. The infant sock 100 includes a generally foot-shaped sock member 111. The sock member 111 includes an upper surface 118, a lower surface 116, and a toe surface 114. The toe surface 114 forms an enclosed end of the upper surface 118, and the lower surface 116. The sock member 111 is preferably constructed of a natural fabric material, such as cotton, or a synthetic fabric material, such as Lyca or spandex, or a combination of such materials. Preferably the infant sock 100 is latex free. The infant sock 100 is preferably sized to fit an infant learning to crawl. A typical age for such an infant is about four months of age to about one year of age.

A gripper member 112 is adhered to the lower surface 116, the upper surface 118, and the toe surface 114. The gripper member 112 can be formed as a tread pattern composed of a series of spaced ribs 113 extending transverse to a length of the sock member 111. The ribs 113 may be spaced along the lower surface 116, and may extend to the upper surface 118, and the toe surface 114. Preferably the gripper member 112 covers an area of the sock member 111 extending from a seam on the upper surface 118 (not shown) at the toe surface 114 to a front-to-mid section of the lower surface 116 of the sock member 111. The area covered by the gripper member 112 on the lower surface 116 is preferably greater than the area covered by the gripper member 112 on the upper surface 118. The gripper member 112 may extend back to a heel portion 115 of the sock member 111. The gripper member 112 preferably covers most of the fabric material of the toe surface 114. The transverse ribs 113 on the toe surface 114 may extend completely around the circumference of the toe surface 114. The gripper member 112 is preferably constructed of a material that increases the coefficient of friction between the materials of the toe surface 114 and the gripper member 112. The material of the gripper member 112 is flexible and withstands laundering. The material of the gripper member 112 may be adhered to the sock member 111 by a thermal process, such as an applique process.

The sock member 111 also includes a tubular elastic band 122 for receiving the infant's foot that also aids in keeping the sock member 111 in place on the infant's lower leg (not shown). The elastic band 122 preferably contains a fabric sheath for comfort. An emblem or similar indicia 120 can be affixed to the sock member 111. The emblem 120 may be constructed of the same material as the gripper member 112. A packaging tab 124 can be attached to the sock member 111 as desired.

What is claimed is:

1. An infant sock for crawling infants comprising: a sock member sized to fit a foot of an infant learning to crawl, said sock member having an exterior upper surface and an exterior lower surface extending between an open end and a closed end, said closed end having an exterior toe surface; and a gripper member connected to said sock member, said gripper member covering at least a portion of each of said exterior upper surface, said exterior lower surface and said exterior toe surface, said gripper member having a coefficient of friction greater than a coefficient of friction of any of said exterior surfaces of said sock member whereby said gripper member covering at least one of said at least a portion of said exterior upper surface and said exterior toe surface provides increased traction to an infant crawling on a smooth surface.

2. The infant sock according to claim 1 wherein said sock member has a tubular shape.

3. The infant sock according to claim 1 wherein said sock member has a foot shape.

4. The infant sock according to claim 1 wherein said gripper member does not extend beyond a front-to-mid section of said exterior lower surface of said sock member.

5. The infant sock according to claim 1 wherein said gripper member is formed from a rubberized material.

6. The infant sock according to claim 1 wherein said gripper member is adhered to said sock member by a thermal process.

7. The infant sock according to claim 1 wherein said gripper member is a continuous member.

8. The infant sock according to claim 1 wherein said gripper member has a plurality of spaced apart ribs extending transverse to a length of said sock member.

9. The infant sock according to claim 8 wherein at least one of said ribs extends around a circumference of said exterior toe surface.

10. The infant sock according to claim 1 including an elastic band attached adjacent said open end of said sock member.

11. The infant sock according to claim 1 including an entrance band attached at said open end of said sock member.

12. An infant sock for crawling infants comprising: a sock member sized to fit a foot of an infant learning to crawl, said sock member having an exterior upper surface and an exterior lower surface extending between an open end and a closed end, said closed end having an exterior toe surface; a gripper member connected to said sock member, said gripper member covering at least a portion of each of said exterior upper surface, said exterior lower surface and said exterior toe surface, said gripper member having a coefficient of friction greater than a coefficient of friction of any of said exterior surfaces of said sock member; and
Piggy Pushers v. Skidders Footwear

544 Fed. Appx. 984 (Fed. Cir. 2013)

Per Curiam

Piggy Pushers sued Skidders Footwear ... for patent infringement. After construing the asserted claims and granting summary judgment of noninfringement, the district court entered final judgment in favor of Skidders. Piggy Pushers appeals. For the reasons set forth below, we affirm.

Background

Piggy Pushers owns U.S. Patent No. 6,385,779, which is directed to infant socks with “gripper” surfaces that provide traction for crawling and walking. Each claimed sock is infant-sized and includes a gripper—a friction-enhancing material, such as rubber—covering at least a portion of the upper, lower, and toe surfaces of the sock. The placement of the gripper surface allows it to touch the floor whether the infant is crawling (when part of the top of the foot, or the toes, touch the floor) or walking (when the bottom of the foot touches the floor), thus distinguishing prior-art socks that allegedly provided traction only on the bottom of the sock. Claim 1 is representative .... Figures 2 and 3 of the ’779 patent depict alternative embodiments of the claimed inventions, showing both tube- and foot-shaped socks, as well as gripper surfaces composed of a single piece of frictional material, e.g., 12, or a series of ribs, e.g., 113[.]

On July 6, 2010, Piggy Pushers brought suit against Skidders for allegedly infringing the ’779 patent. Skidders makes footwear, including the accused product for twelvemonth-old children, pictured [at right.] The product consists of a foot-surrounding sock bonded to a rubber outsole.

On March 5, 2012, the district court issued its opinion construing various terms of the ’779 patent. First, the court construed the preamble of each claim at issue as limiting the claimed invention as a whole to a “sock.” As to
the meaning of the term “sock,” the court said that “[n]othing in the claim language or the specifications suggests that the inventor intended ‘sock’ to mean anything other than what a person of ordinary skill in the art of footwear would understand it to mean.” The court then said that it was construing “sock” to mean “a knitted or woven covering for the foot”—even while indicating that the ordinary meaning governed to distinguish a shoe. The court construed “sock member” to mean “a part of the sock” and construed “a sock member sized to fit a foot of an infant learning to crawl” to mean “a sock member of a size such that it conforms to the foot of an infant learning to crawl.” Neither party argued that “gripper member” required construction; accordingly, the court did not construe that phrase.

On August 6, 2012, Skidders moved for summary judgment of noninfringement, which the district court granted on November 2, 2012. The district court recited evidence that the accused product has various qualities consistent with shoes—such as a thick, durable outsole, a separate insole, a fixed size and shape, a design not intended to be worn inside a shoe, and left-foot and right-foot designations—evidence to which Piggy Pushers “raised few challenges.” At the same time, the district court noted that there was “no dispute that the Accused Product consists of a sock that has been bonded to a rubber outsole”; that Skidders had described the accused product as “sock-like,” as a “sock with rubber outsole,” and as a “hybrid sockshoe design”; and that “retailers could not decide whether to put [the accused product] in the hosiery department or the shoe department.”

Considering the evidence presented, the district court concluded that Piggy Pushers was entitled to summary judgment of noninfringement. Although Piggy Pushers had shown “a question of fact as to whether the Accused Product is a hybrid shoe and sock,” the court reasoned, the ’779 patent “addresses a sock,” not “a hybrid sockshoe,” and there was “simply no evidence from which a reasonable jury could conclude that [Skidders’s] product is a sock.” That conclusion—which appears to have relied on the ordinary meaning of “sock” in addition to the “knitted or woven covering for the foot” language of the claim-construction opinion—sufficed for summary judgment of noninfringement. As an alternative basis for granting summary judgment, the district court agreed with Skidders that “any reasonable jury would find that because the sock member of the Accused Product is bonded to a rigid rubber sole, the sock portion of the Accused Product does not conform to the foot,” as required by the district court’s construction. For those reasons, the district court entered judgment in favor of Skidders, a judgment that became final upon the stipulated dismissal of counterclaims without prejudice.

Piggy Pushers appeals. …

Discussion

Piggy Pushers challenges the district court’s construction of the preambles as limiting the claims, its conclusion that no reasonable jury could find that the accused product is a “sock,” and its conclusion that no reasonable jury could find that the sock portion of the accused product conforms to the foot. We review the district court’s claim construction and its grant of summary judgment de novo.
A

Because some preambles are limiting and others not, we focus on the sole concrete issue at stake in deciding whether the particular preambles here are limiting—namely, whether, when the elements recited in the body of the claims are combined as claimed, the result must itself be a sock. We think the answer plain from the specification, which uniformly describes what results from combining the sock member with the gripper member as itself remaining a “sock.” In particular, the specification distinguishes a sock from a “shoe,” which can be undesirable or difficult to put on an infant; so the addition of the gripper cannot transform the sock into a shoe. More generally, introducing the invention, the specification explains that “socks can be disadvantageous on smooth floor surfaces *** because there is a very low coefficient of friction between fabric material of the socks and the floor surface,” (emphasis added), and that the inventors have conceived and described a particular kind of “sock” that overcomes that problem, without the use of a “shoe,” and does so for crawling infants, not just those who can walk.

The requirement that the combined elements form a “sock” is a “fundamental characteristic of the claimed invention.” Poly-Am., L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed. Cir. 2004). We therefore affirm the construction of the preambles as limiting to the extent necessary to express the idea that the claims each cover a sock, not a shoe or another article that may be derivative or partly made up of a sock but is not itself a sock. See Am. Med. Sys., Inc. v. Biolitec, Inc., 618 F.3d 1354, 1358 (Fed. Cir. 2010) (“Whether to treat a preamble term as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.”).

B

That conclusion decides this case, because “[n]o reasonable juror could conclude that the Accused Product is a sock as defined in the patent.” D. Ct. (emphasis added). Once the preamble language is accepted as a limitation of the whole product to a “sock,” Piggy Pushers’s only meaningful argument about whether the accused product is a “sock” relies on “sock” having only the meaning of “a knitted or woven covering for the foot.” But that approach, while understandable given some aspects of the district court’s claim construction opinion, is not ultimately sensible considering the full context of the patent and the litigation.

The “knitted or woven covering” formulation is necessarily incomplete. If it meant to exclude all non-knitted and non-woven components, it could not fit this patent, which is all about adding such components. Once it is acknowledged that additions to the knitted or woven material are allowed, nothing in the “knitted or woven covering” formulation itself supplies a principle to identify what additions are allowed. Yet there must be such a limit, given the undisputed exclusion of shoes—which can readily include foot coverings made of woven material such as canvas.

For such reasons, the governing construction of “sock” must, instead, include its ordinary meaning, captured centrally but not exclusively by the knitted-or-woven covering language. That is evidently how the district court understood the construction it was applying on summary judgment: the ultimate product must remain a “sock” in its ordinary meaning, even with the addition of friction-enhancing com-
ponents. Importantly, Piggy Pushers does not argue here that there was a change of construction that unfairly denied it the opportunity to present evidence—which it plainly did present—on whether the accused product was covered by the fuller understanding of “sock” that incorporated the word’s ordinary meaning.

Under that construction, Piggy Pushers has no challenge to the summary-judgment ruling. It argues that the accused product includes a sock, but that is not enough. It had evidence that Skidders sometimes described the product as a “sock with rubber outsole,” or in similar terms, but never simply as a sock. It had evidence, too, that “retailers could not decide whether to put [it] in the hosiery department or the shoe department.” But such evidence showed at most a hybrid character of the product. Piggy Pushers had no evidence to respond to Skidders’s evidence that the product, with its rigid rubber sole severely constraining flexibility in shape and size, was not a “sock” under that term’s ordinary meaning, applied within the context of this patent. In these circumstances, there is no evidence from which a jury could reasonably find that the product actually is a sock.

In light of that conclusion, we need not reach the district court’s alternative ground of decision, concerning a requirement that a covered product conform to the foot.

...
(b) a tea composition comprising from about 2 grams to about 10 grams of tea having a particle size of from about 0.40 mm to about 0.75 mm.

II. District Court Proceedings

Teashot accuses Green Mountain’s tea-brewing K-Cups of infringing the ‘672 patent. The accused K-Cup has a foil lid, which would be punctured by a needle to inject water during use.

The district court construed the claim element “sealed body is constructed of a water-permeable material which allows flow of a fluid through said sealed body to produce a tea extract from said tea composition” as “the portions of the sealed body into which fluid flows and out of which fluid flows are water-permeable material allowing flow of a fluid through said sealed body to produce a tea extract from said tea composition.” The district court concluded that the K-Cups do not literally infringe because the K-Cups do not have a “water-permeable material” for water to flow into the sealed bodies. ... The district court therefore entered summary judgment of non-infringement in favor of Green Mountain.

Teashot appeals the claim construction and summary judgment of no literal infringement ...

Discussion

I. Claim Construction

... 

Teashot argues that the district court’s construction deviates from the claim text and improperly imports limitations from the specification by requiring fluid to flow into and out of the sealed body through water-permeable material. Green Mountain counters that the phrase “which allows,” linking “water-permeable material” to the “flow of a fluid through said sealed body,” requires that fluid flows through the “sealed body” via the “water-permeable material.”

We agree with Green Mountain that the claim text identifies “water-permeable material” as the means through which fluid could flow through the “sealed body.” The specification confirms this conclusion. Every discussion in the specification of fluid flowing through the “sealed body” refers to the “water-permeable material.” The ’672 patent mentions no other means through which fluid could flow through the “sealed body.”

Teashot contends, however, that Figure 4 in the ’672 patent teaches an embodiment in which water enters a sealed body through an opening in a material that is not otherwise permeable to water. Teashot further contends that the district court’s claim construction improperly excludes this embodiment in Figure 4.
Figure 4, however, is limited to disclosing an arrangement in which multiple tea containers can be accessed individually to add different tea compositions, but used together for brewing. Figure 4 and its descriptions do not show any details of entry or exit means in the containers for water to flow through. From this silence, we cannot assume Figure 4 to depart from the consistent teachings elsewhere in the ’672 patent that water can flow through a “sealed body” via a “water-permeable material.” We are therefore not persuaded by Teashot that the district court erred in construing this claim element.

II. Summary Judgment of Non-Infringement

... 

Literal infringement requires that “every limitation set forth in a claim must be found in an accused product, exactly.” Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995).

Teashot does not dispute that its owner and the inventor of the ’672 patent, in testimonies quoted by Green Mountain, admitted that the lid of the K-Cup is not water permeable. Teashot also does not dispute the following admission that the mere puncturing of the K-Cup lid fails to transform the material into a water-permeable material:

Q Correct me if I’m wrong, when you puncture the foil lid, the actual foil remains water impermeable, correct?
A The—the foil around the hole, yes.
Q Yes. The hole no longer has foil in it, correct?
A Correct.
Q Hence the hole.
A Right.
Q The water doesn’t flow through the foil; it flows through an open space. Correct?
A Correct.

Appellee Br. 31 (quoting Joint Appndx. A1203).

Nevertheless, Teashot contends that a factual dispute remains as to whether the K-Cup’s lid, once punctured, becomes a “water-permeable material.” Teashot cites no support in the record that a skilled artisan would consider “water-permeable material” to encompass material not permeable to water but having merely a puncture hole. We do not find Teashot’s unsupported arguments—especially against its admissions quoted by Green Mountain—create a genuine factual dispute sufficient to survive summary judgment.

... 

Claim Definiteness


Claims are property boundaries. If one can’t definitively construe a claim, and thus discern proper public notice of what’s inside and what’s outside the exclusion
zone, the claim fails of its essential purpose. At the same time, the mere fact that a claim construction question is tough can’t be enough, by itself, to invalidate a claim; if it were, a significant number of extant patent claims would not survive scrutiny. The claim definiteness requirement embodied in § 112(b) entails balancing these considerations. Secondarily, the claim definiteness requirement helps cabin a particular type of patent claim, known as a “means plus function” claim, to its proper scope. The cases below begin with the need for a definitive boundary, then turn to the rigors of mean-plus-function claiming.

**Nautilus, Inc. v. Biosig Instruments, Inc.**

134 S. Ct. 2120 (2014)

Ginsburg, Justice:

The Patent Act requires that a patent specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.” 35 U.S. C. § 112, ¶ 2 (2006 ed.) (emphasis added). This case, involving a heartrate monitor used with exercise equipment, concerns the proper reading of the statute’s clarity and precision demand. …

I

Authorized by the Constitution “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to *** Inventors the exclusive Right to their *** Discoveries,” Art. I, §8, cl. 8, Congress has enacted patent laws rewarding inventors with a limited monopoly. “Th[at] monopoly is a property right,” and “like any property right, its boundaries should be clear.” *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 535 U.S. 722, 730 (2002). See also *Markman v. Westview Instruments*, 517 U.S. 370, 373 (1996) (“It has long been understood that a patent must describe the exact scope of an invention and its manufacture *** .”). Thus, when Congress enacted the first Patent Act in 1790, it directed that patent grantees file a written specification “containing a description *** of the thing or things *** invented or discovered,” which “shall be so particular” as to “distinguish the invention or discovery from other things before known and used.” Act of Apr. 10, 1790, § 2, 1 Stat. 110.

The patent laws have retained this requirement of definiteness even as the focus of patent construction has shifted. Under early patent practice in the United States, we have recounted, it was the written specification that “represented the key to the patent.” *Markman*, 517 U.S. at 379. Eventually, however, patent applicants began to set out the invention’s scope in a separate section known as the “claim.” See generally 1 R. Moy, *Walker on Patents* § 4.2, pp. 4-17 to 4-20 (4th ed. 2012). The Patent Act of 1870 expressly conditioned the receipt of a patent on the inventor’s inclusion of one or more such claims, described with particularity and distinctness. See Act of July 8, 1870, § 26, 16 Stat. 201 (to obtain a patent, the inventor must “particularly point out and distinctly claim the part, improvement, or combination which [the inventor] claims as his invention or discovery”).

The 1870 Act’s definiteness requirement survives today, largely unaltered. Section 112 of the Patent Act of 1952, applicable to this case, requires the patent applicant to conclude the specification with “one or more claims particularly pointing out
and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2 (2006 ed.). A lack of definiteness renders invalid “the patent or any claim in suit.” § 282, ¶ 2(3).

II

A

The patent in dispute, U.S. Patent No. 5,337,753, issued to Dr. Gregory Lekhtman in 1994 and assigned to respondent Biosig Instruments, Inc., concerns a heart-rate monitor for use during exercise. Previous heart-rate monitors, the patent asserts, were often inaccurate in measuring the electrical signals accompanying each heartbeat (electrocardiograph or ECG signals). The inaccuracy was caused by electrical signals of a different sort, known as electromyogram or EMG signals, generated by an exerciser’s skeletal muscles when, for example, she moves her arm, or grips an exercise monitor with her hand. These EMG signals can “mask” ECG signals and thereby impede their detection.

Dr. Lekhtman’s invention claims to improve on prior art by eliminating that impediment. The invention focuses on a key difference between EMG and ECG waveforms: while ECG signals detected from a user’s left hand have a polarity opposite to that of the signals detected from her right hand, EMG signals from each hand have the same polarity. The patented device works by measuring equalized EMG signals detected at each hand and then using circuitry to subtract the identical EMG signals from each other, thus filtering out the EMG interference.

As relevant here, the ’753 patent describes a heart-rate monitor contained in a hollow cylindrical bar that a user grips with both hands, such that each hand comes into contact with two electrodes, one “live” and one “common.” The device is illustrated in figure 1 of the patent, reproduced [above].

Claim 1 of the ’753 patent, which contains the limitations critical to this dispute, refers to a “heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures.” The claim “comprise[s],” among other elements, an “elongate member” (cylindrical bar) with a display device; “electronic circuitry including a difference amplifier”; and, on each half of the cylindrical bar, a live electrode and a common electrode “mounted *** in spaced relationship with each other.” The claim sets forth additional elements, including that the cylindrical bar is

\[\text{Figure 1}\]

to be held in such a way that each of the user’s hands “contact[s]” both electrodes on each side of the bar. Further, the EMG signals detected by the two electrode pairs are to be “of substantially equal magnitude and phase” so that the difference amplifier will “produce a substantially zero [EMG] signal” upon subtracting the signals from one another.

B

The dispute between the parties arose in the 1990’s, when Biosig allegedly disclosed the patented technology to StairMaster Sports Medical Products, Inc. According to Biosig, StairMaster, without ever obtaining a license, sold exercise machines that included Biosig’s patented technology, and petitioner Nautilus, Inc., continued to do so after acquiring the StairMaster brand. In 2004, based on these allegations, Biosig brought a patent infringement suit against Nautilus … .

With Biosig’s lawsuit launched, Nautilus asked the [PTO] to reexamine the ’753 patent. The reexamination proceedings centered on whether the patent was anticipated or rendered obvious by prior art—principally, a patent issued in 1984 to an inventor named Fujisaki, which similarly disclosed a heart-rate monitor using two pairs of electrodes and a difference amplifier. Endeavoring to distinguish the ’753 patent from prior art, Biosig submitted a declaration from Dr. Lekhtman. The declaration attested, among other things, that the ’753 patent sufficiently informed a person skilled in the art how to configure the detecting electrodes so as “to produce equal EMG [signals] from the left and right hands.” Although the electrodes’ design variables—including spacing, shape, size, and material—cannot be standardized across all exercise machines, Dr. Lekhtman explained, a skilled artisan could undertake a “trial and error” process of equalization. This would entail experimentation with different electrode configurations in order to optimize EMG signal cancellation. In 2010, the PTO issued a determination confirming the patentability of the ’753 patent’s claims.

Biosig thereafter reinstituted its infringement suit, which the parties had voluntarily dismissed without prejudice while PTO reexamination was underway. In 2011, the District Court conducted a hearing to determine the proper construction of the patent’s claims … . According to Biosig, th[e] “spaced relationship” referred to the distance between the live electrode and the common electrode in each electrode pair. Nautilus, seizing on Biosig’s submissions to the PTO during the reexamination, maintained that the “spaced relationship” must be a distance “greater than the width of each electrode.” The District Court ultimately construed the term to mean “there is a defined relationship between the live electrode and the common electrode on one side of the cylindrical bar and the same or a different defined relation-

4 Dr. Lekhtman’s declaration also referred to an expert report prepared by Dr. Henrietta Galiana, Chair of the Department of Biomedical Engineering at McGill University, for use in the infringement litigation. That report described how Dr. Galiana’s laboratory technician, equipped with a wooden dowel, wire, metal foil, glue, electrical tape, and the drawings from the ’753 patent, was able in two hours to build a monitor that “worked just as described in the *** patent.”
ship between the live electrode and the common electrode on the other side of the cylindrical bar,” without any reference to the electrodes’ width.

Nautilus moved for summary judgment, arguing that the term “spaced relationship,” as construed, was indefinite under § 112, ¶ 2. The District Court granted the motion. Those words, the District Court concluded, “did not tell [the court] or anyone what precisely the space should be,” or even supply “any parameters” for determining the appropriate spacing.

The Federal Circuit reversed and remanded. A claim is indefinite, the majority opinion stated, “only when it is ‘not amenable to construction’ or ‘insolubly ambiguous.’” 715 F.3d 891, 898 (2013) (quoting Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005)). Under that standard, the majority determined, the ’753 patent survived indefiniteness review. Considering first the “intrinsic evidence”—i.e., the claim language, the specification, and the prosecution history—the majority discerned “certain inherent parameters of the claimed apparatus, which to a skilled artisan may be sufficient to understand the metes and bounds of ‘spaced relationship.’” Id. at 899. These sources of meaning, the majority explained, make plain that the distance separating the live and common electrodes on each half of the bar “cannot be greater than the width of a user’s hands”; that is so “because claim 1 requires the live and common electrodes to independently detect electrical signals at two distinct points of a hand.” Id. Furthermore, the majority noted, the intrinsic evidence teaches that this distance cannot be “infinitesimally small, effectively merging the live and common electrodes into a single electrode with one detection point.” Id. The claim’s functional provisions, the majority went on to observe, shed additional light on the meaning of “spaced relationship.” Surveying the record before the PTO on reexamination, the majority concluded that a skilled artisan would know that she could attain the indicated functions of equalizing and removing EMG signals by adjusting design variables, including spacing.

In a concurring opinion, Judge Schall reached the majority’s result employing “a more limited analysis.” Id. at 905. …

III

A

Although the parties here disagree on the dispositive question—does the ’753 patent withstand definiteness scrutiny—they are in accord on several aspects of the § 112, ¶ 2 inquiry. First, definiteness is to be evaluated from the perspective of someone skilled in the relevant art. Second, in assessing definiteness, claims are to be read in light of the patent’s specification and prosecution history. Third, “[d]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed.” Brief for Respondent 55 (emphasis added).

The parties differ, however, in their articulations of just how much imprecision § 112, ¶ 2 tolerates. In Nautilus’ view, a patent is invalid when a claim is “ambiguous, such that readers could reasonably interpret the claim’s scope differently.” Brief for Petitioner 37. Biosig and the Solicitor General would require only that the patent provide reasonable notice of the scope of the claimed invention. See Brief for Respondent 18; Brief for United States as Amicus Curiae 9-10.
Section 112, we have said, entails a “delicate balance.” Festo, 535 U.S. at 731. On the one hand, the definiteness requirement must take into account the inherent limitations of language. See id. Some modicum of uncertainty, the Court has recognized, is the “price of ensuring the appropriate incentives for innovation.” Id. at 732. One must bear in mind, moreover, that patents are “not addressed to lawyers, or even to the public generally,” but rather to those skilled in the relevant art. Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902) (also stating that “any description which is sufficient to apprise [steel manufacturers] in the language of the art of the definite feature of the invention, and to serve as a warning to others of what the patent claims as a monopoly, is sufficiently definite to sustain the patent”).

At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby “‘appris[ing] the public of what is still open to them.’” Markman, 517 U.S. at 373 (quoting McClain v. Ortmayer, 141 U.S. 419, 424 (1891)). Otherwise there would be “[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.” United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942). And absent a meaningful definiteness check, we are told, patent applicants face powerful incentives to inject ambiguity into their claims. Eliminating that temptation is in order, and “the patent drafter is in the best position to resolve the ambiguity in *** patent claims.” Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read § 112, ¶ 2 to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that “the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.” Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916). See also United Carbon, 317 U.S. at 236 (“claims must be reasonably clear-cut”); Markman, 517 U.S. at 389 (claim construction calls for “the necessarily sophisticated analysis of the whole document,” and may turn on evaluations of expert testimony).

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6 See also United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942) (“The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise.”); General Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938) (“The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.”).
In resolving Nautilus’ definiteness challenge, the Federal Circuit asked whether the '753 patent’s claims were “amenable to construction” or “insolubly ambiguous.” Those formulations can breed lower court confusion, for they lack the precision § 112, ¶ 2 demands. It cannot be sufficient that a court can ascribe some meaning to a patent’s claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc. To tolerate imprecision just short of that rendering a claim “insolubly ambiguous” would diminish the definiteness requirement’s public-notice function and foster the innovation-discouraging “zone of uncertainty,” United Carbon, 317 U.S. at 236, against which this Court has warned.

Appreciating that “terms like ‘insolubly ambiguous’ may not be felicitous,” Brief for Respondent 34, Biosig argues the phrase is a shorthand label for a more probing inquiry that the Federal Circuit applies in practice. The Federal Circuit’s fuller explications of the term “insolubly ambiguous,” we recognize, may come closer to tracking the statutory prescription. See, e.g., 715 F.3d at 898 (case below) (“[I]f reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness.”). But although this Court does not “micromanag[e] the Federal Circuit’s particular word choice” in applying patent-law doctrines, we must ensure that the Federal Circuit’s test is at least “probative of the essential inquiry.” Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 40 (1997). Falling short in that regard, the expressions “insolubly ambiguous” and “amenable to construction” permeate the Federal Circuit’s recent decisions concerning § 112, ¶ 2’s requirement. We agree with Nautilus and its amici that such terminology can leave courts and the patent bar at sea without a reliable compass.10

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10 The Federal Circuit suggests that a permissive definiteness standard “accords respect to the statutory presumption of patent validity.” 715 F.3d at 902. See also § 282, ¶ 1 (“[a] patent shall be presumed valid,” and “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity”); Microsoft Corp. v. i4i Ltd., 131 S. Ct. 2238, 2242 (2011) (invalidity defenses must be proved by “clear and convincing evidence”). As the parties appear to agree, however, this presumption of validity does not alter the degree of clarity that § 112, ¶ 2 demands from patent applicants; to the contrary, it incorporates that definiteness requirement by reference. See § 282, ¶ 2(3) (defenses to infringement actions include “[i]nvalidity of the patent or any claim in suit for failure to comply with *** any requirement of [§ 112]”).

The parties nonetheless dispute whether factual findings subsidiary to the ultimate issue of definiteness trigger the clear-and-convincing evidence standard and, relatedly, whether deference is due to the PTO’s resolution of disputed issues of fact. We leave these questions for another day. The court below treated definiteness as “a legal issue [the] court reviews without deference,” 715 F.3d at 897, and Biosig
IV

Both here and in the courts below, the parties have advanced conflicting arguments as to the definiteness of the claims in the '753 patent. Nautilus maintains that the claim term “spaced relationship” is open to multiple interpretations reflecting markedly different understandings of the patent’s scope, as exemplified by the disagreement among the members of the Federal Circuit panel. Biosig responds that “spaced relationship,” read in light of the specification and as illustrated in the accompanying drawings, delineates the permissible spacing with sufficient precision.

“[M]indful that we are a court of review, not of first view,” Cutter v. Wilkinson, 544 U.S. 709, 718 n.7 (2005), we decline to apply the standard we have announced to the controversy between Nautilus and Biosig. As we have explained, the Federal Circuit invoked a standard more amorphous than the statutory definiteness requirement allows. We therefore follow our ordinary practice of remanding so that the Court of Appeals can reconsider, under the proper standard, whether the relevant claims in the '753 patent are sufficiently definite.

... 

Teva Pharm. USA, Inc. v. Sandoz, Inc.

135 S. Ct. 831 (2015)

Breyer, Justice:

In Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), we explained that a patent claim is that “portion of the patent document that defines the scope of the patentee’s rights.” Id. at 372. We held that “the construction of a patent, including terms of art within its claim,” is not for a jury but “exclusively” for “the court” to determine. Id. That is so even where the construction of a term of art has “evidentiary underpinnings.” Id. at 390.

Today’s case involves claim construction with “evidentiary underpinnings.” And, it requires us to determine what standard the Court of Appeals should use when it reviews a trial judge’s resolution of an underlying factual dispute. Should the Court of Appeals review the district court’s factfinding de novo as it would review a question of law? Or, should it review that factfinding as it would review a trial judge’s factfinding in other cases, namely by taking them as correct “unless clearly erroneous?” See Fed. Rule Civ. Proc. 52(a)(6). We hold that the appellate court must apply a “clear error,” not a de novo, standard of review.

I

The basic dispute in this case concerns the meaning of the words “molecular weight” as those words appear in a patent claim. The petitioners, Teva Pharmaceuticals (along with related firms), own the relevant patent. The patent covers a manufacturing method for Copaxone, a drug used to treat multiple sclerosis. The drug’s active ingredient, called “copolymer-1,” is made up of molecules of varying sizes.

...
And the relevant claim describes that ingredient as having “a molecular weight of 5 to 9 kilodaltons.”

The respondents, Sandoz, Inc. (and several other firms), tried to market a generic version of Copaxone. Teva sued Sandoz for patent infringement. Sandoz defended the suit by arguing that the patent was invalid. The Patent Act requires that a claim “particularly point out and distinctly claim the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 ¶ 2 (2006 ed.); see Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2125, n. 1 (2014). The phrase “molecular weight of 5 to 9 kilodaltons,” said Sandoz, did not satisfy this requirement.

The reason that the phrase is fatally indefinite, Sandoz argued, is that, in the context of this patent claim, the term “molecular weight” might mean any one of three different things. The phrase might refer (1) to molecular weight as calculated by the weight of the molecule that is most prevalent in the mix that makes up copolymer-1. (The scientific term for molecular weight so calculated is, we are told, “peak average molecular weight.”) The phrase might refer (2) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer-1 and calculating the average weight, i.e., adding up the weight of each molecule and dividing by the number of molecules. (The scientific term for molecular weight so calculated is, we are told, “number average molecular weight.”) Or, the phrase might refer (3) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer-1 and calculating their average weight while giving heavier molecules a weight-related bonus when doing so. (The scientific term for molecular weight so calculated, we are told, is “weight average molecular weight.”) In Sandoz’s view, since Teva’s patent claim does not say which method of calculation should be used, the claim’s phrase “molecular weight” is indefinite, and the claim fails to satisfy the critical patent law requirement.

The District Court, after taking evidence from experts, concluded that the patent claim was sufficiently definite. Among other things, it found that in context a skilled artisan would understand that the term “molecular weight” referred to molecular weight as calculated by the first method, i.e., “peak average molecular weight.” In part for this reason, the District Court held the patent valid.

On appeal, the Federal Circuit held to the contrary. It found that the term “molecular weight” was indefinite. And it consequently held the patent invalid. In reaching this conclusion, the Federal Circuit reviewed de novo all aspects of the District Court’s claim construction, including the District Court’s determination of subsidiary facts.

Teva filed a petition for certiorari. And we granted that petition. The Federal Circuit reviews the claim construction decisions of federal district courts throughout the Nation, and we consequently believe it important to clarify the standard of review that it must apply when doing so.
Federal Rule of Civil Procedure 52(a)(6) states that a court of appeals “must not set aside” a district court’s “[f]indings of fact” unless they are “clearly erroneous.” In our view, this rule and the standard it sets forth must apply when a court of appeals reviews a district court’s resolution of subsidiary factual matters made in the course of its construction of a patent claim. We have made clear that the Rule sets forth a “clear command.” Anderson v. Bessemer City, 470 U.S. 564, 574 (1985). “It does not make exceptions or purport to exclude certain categories of factual findings from the obligation of a court of appeals to accept a district court’s findings unless clearly erroneous.” Pullman-Standard v. Swint, 456 U.S. 273, 287 (1982). Accordingly, the Rule applies to both subsidiary and ultimate facts. And we have said that, when reviewing the findings of a “district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues de novo.” Anderson, 470 U.S. at 573 (quoting Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 123 (1969) [a patent case]).

Our opinion in Markman neither created, nor argued for, an exception to Rule 52(a). The question presented in that case was a Seventh Amendment question: Should a jury or a judge construe patent claims? 517 U.S. at 372. We pointed out that history provides no clear answer. Id. at 388. The task primarily involves the construction of written instruments. Id. at 386, 388, 389. And that task is better matched to a judge’s skills. Id. at 388 (“The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis”). We consequently held that claim construction falls “exclusively within the province of the court,” not that of the jury. Id. at 372.

When describing claim construction we concluded that it was proper to treat the ultimate question of the proper construction of the patent as a question of law in the way that we treat document construction as a question of law. Id. at 388-391. But this does not imply an exception to Rule 52(a) for underlying factual disputes. We used the term “question of law” while pointing out that a judge, in construing a patent claim, is engaged in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs. Id. at 384, 386, 388, 389; see also Motion Picture Patents Co. v. Universal Film Mfg., 243 U.S. 502, 510 (1917) (patent claims are “aptly likened to the description in a deed, which sets the bounds to the grant which it contains”); Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227 (1880) (analogizing patent construction to the construction of other written instruments like contracts). Construction of written instruments often presents a “question solely of law,” at least when the words in those instruments are “used in their ordinary meaning.” Great Northern R. Co. v. Merchants Elevator Co., 259 U.S. 285, 291 (1922). But sometimes, say when a written instrument uses “technical words or phrases not commonly understood,” id. at 292, those words may give rise to a factual dispute. If so, extrinsic evidence may help to “establish a usage of trade or locality.” Id. And in that circumstance, the “determination of the matter of fact” will “preced[e]” the “function of construction.” Id.; see also 12 R.
Lord, Williston on Contracts §§ 34:1, 34:19 (4th ed. 2012) (In contract interpretation, the existence of a “usage”—a “practice or method” in the relevant industry—“is a question of fact”) (internal quotation marks omitted). This factual determination, like all other factual determinations, must be reviewed for clear error. See Pullman-Standard, 456 U.S. at 287 (The Rule does not “exclude certain categories of factual findings” and applies to both “subsidiary” and “ultimate” facts).

Accordingly, when we held in Markman that the ultimate question of claim construction is for the judge and not the jury, we did not create an exception from the ordinary rule governing appellate review of factual matters. Markman no more creates an exception to Rule 52(a) than would a holding that judges, not juries, determine equitable claims, such as requests for injunctions. A conclusion that an issue is for the judge does not indicate that Rule 52(a) is inapplicable.

While we held in Markman that the ultimate issue of the proper construction of a claim should be treated as a question of law, we also recognized that in patent construction, subsidiary factfinding is sometimes necessary. Indeed, we referred to claim construction as a practice with “evidentiary underpinnings,” a practice that “falls somewhere between a pristine legal standard and a simple historical fact.” 517 U.S. at 378, 388. We added that sometimes courts may have to make “credibility judgments” about witnesses. Id. at 389. In other words, we recognized that courts may have to resolve subsidiary factual disputes. And, as explained above, the Rule requires appellate courts to review all such subsidiary factual findings under the “clearly erroneous” standard.

Finally, practical considerations favor clear error review. We have previously pointed out that clear error review is “particularly” important where patent law is at issue because patent law is “a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.” Graver Tank & Mfg. v. Linde Air Prods., 339 U.S. 605, 610 (1950). A district court judge who has presided over, and listened to, the entirety of a proceeding has a comparatively greater opportunity to gain that familiarity than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred.

B

Sandoz argues that claim construction mostly consists of construing a set of written documents that do not give rise to subsidiary factual disputes. It adds that separating “factual” from “legal” questions is often difficult. And Sandoz, like the Federal Circuit itself, argues that it is simpler for that appellate court to review the entirety of the district court’s claim construction de novo rather than to apply two separate standards.

But even were we free to ignore the Federal Rule (which we are not), we would not find this argument convincing. Courts of appeals have long found it possible to separate factual from legal matters. At the same time, the Federal Circuit’s efforts to treat factual findings and legal conclusions similarly have brought with them their own complexities.
Finally, the Circuit feared that “clear error” review would bring about less uniformity. Neither the Circuit nor Sandoz, however, has shown that (or explained why) divergent claim construction stemming from divergent findings of fact (on subsidiary matters) should occur more than occasionally. After all, the Federal Circuit will continue to review de novo the district court’s ultimate interpretation of the patent claims. And the attorneys will no doubt bring cases construing the same claim to the attention of the trial judge; those prior cases will sometimes be binding because of issue preclusion, see Markman, 517 U.S. at 391, and sometimes will serve as persuasive authority. Moreover, it is always possible to consolidate for discovery different cases that involve construction of the same claims. And, as we said in Markman, subsidiary factfinding is unlikely to loom large in the universe of litigated claim construction. Id. at 389-390.

C

The dissent argues that claim construction does not involve any “factfinding,” or, if it does, claim construction factfinding is akin to the factfinding that underlies our interpretation of statutes. Its first, broader contention runs contrary to our recognition in Markman that claim construction has “evidentiary underpinnings” and that courts construing patent claims must sometimes make “credibility judgments” about witnesses. 517 U.S. at 389-390. Indeed, as discussed in Part III, this case provides a perfect example of the factfinding that sometimes underlies claim construction: The parties here presented the District Court with competing fact-related claims by different experts, and the District Court resolved the issues of fact that divided those experts.

The dissent’s contention also runs contrary to Sandoz’s concession at oral argument that claim construction will sometimes require subsidiary factfinding. Tr. of Oral Arg. 33-34, 38-40. It is in tension with our interpretation of related areas of patent law, such as the interpretation of “obviousness,” which we have said involves subsidiary factfinding subject to Rule 52(a)’s clear error review. And it fights the question presented in this case, which assumes the existence of such fact-finding. See Pet. for Cert. i (whether “a district court’s factual finding in support of its construction of a patent claim term may be reviewed de novo, *** or only for clear error”).

Neither do we find factfinding in this context sufficiently similar to the factfinding that underlies statutory interpretation. Statutes, in general, address themselves to the general public; patent claims concern a small portion of that public. Statutes typically (though not always) rest upon congressional consideration of general facts related to a reasonably broad set of social circumstances; patents typically (though not always) rest upon consideration by a few private parties, experts, and administrators of more narrowly circumscribed facts related to specific technical matters. The public, and often an adversarial public, typically considers and discusses the relevant general facts before Congress enacts a statute; only private parties, experts, and administrators likely consider the relevant technical facts before the award of a patent. Given these differences, it is not surprising that this Court has never previously compared patent claim construction in any here relevant way to statutory construction. As discussed [above], however, the Court has repeatedly compared patent
claim construction to the construction of other written instruments such as deeds and contracts.

D

Now that we have set forth why the Federal Circuit must apply clear error review when reviewing subsidiary factfinding in patent claim construction, it is necessary to explain how the rule must be applied in that context. We recognize that a district court’s construction of a patent claim, like a district court’s interpretation of a written instrument, often requires the judge only to examine and to construe the document’s words without requiring the judge to resolve any underlying factual disputes. As all [the] parties [in this case] agree, when the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law, and the Court of Appeals will review that construction de novo.

In some cases, however, the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. See, e.g., Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1871) (a patent may be “so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning”). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the “evidentiary underpinnings” of claim construction that we discussed in Markman, and this subsidiary factfinding must be reviewed for clear error on appeal.

For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review. That is because “[e]xperts may be examined to explain terms of art, and the state of the art, at any given time,” but they cannot be used to prove “the proper or legal construction of any instrument of writing.” Winans v. New York & Erie R. Co., 62 U.S. (21 How.) 88, 100-101 (1859); see also Markman, 517 U.S. at 388 (“Where technical terms are used, or where the qualities of substances *** or any similar data necessary to the comprehension of the language of the patent are unknown to the judge, the testimony of witnesses may be received upon these subjects, and any other means of information be employed. But in the actual interpretation of the patent the court proceeds upon its own responsibility, as an arbiter of the law, giving to the patent its true and final character and force.”” (quoting 2 W. Robinson, Law of Patents § 732 (1890) (emphasis in original).

Accordingly, the question we have answered here concerns review of the district court’s resolution of a subsidiary factual dispute that helps that court determine the proper interpretation of the written patent claim. The district judge, after deciding the factual dispute, will then interpret the patent claim in light of the facts as he has found them. This ultimate interpretation is a legal conclusion. The appellate court can still review the district court’s ultimate construction of the claim de novo. But, to
overturn the judge’s resolution of an underlying factual dispute, the Court of Appeals must find that the judge, in respect to those factual findings, has made a clear error. Fed. Rule Civ. Proc. 52(a)(6).

In some instances, a factual finding will play only a small role in a judge’s ultimate legal conclusion about the meaning of the patent term. But in some instances, a factual finding may be close to dispositive of the ultimate legal question of the proper meaning of the term in the context of the patent. Nonetheless, the ultimate question of construction will remain a legal question. Simply because a factual finding may be nearly dispositive does not render the subsidiary question a legal one. “[A]n issue does not lose its factual character merely because its resolution is dispositive of the ultimate” legal question. Miller v. Fenton, 474 U.S. 104, 113 (1985). It is analogous to a judge (sitting without a jury) deciding whether a defendant gave a confession voluntarily. The answer to the legal question about the voluntariness of the confession may turn upon the answer to a subsidiary factual question, say “whether in fact the police engaged in the intimidation tactics alleged by the defendant.” Id. at 112. An appellate court will review the trial judge’s factual determination about the alleged intimidation deferentially (though, after reviewing the factual findings, it will review a judge’s ultimate determination of voluntariness de novo). See id. at 112-118. An appellate court similarly should review for clear error those factual findings that underlie a district court’s claim construction.

III

We can illustrate our holding by considering an instance in which Teva, with the support of the Solicitor General, argues that the Federal Circuit wrongly reviewed the District Court’s factual finding de novo. See Brief for Petitioners 54-56; Brief for United States as Amicus Curiae 31-32. Recall that Teva’s patent claim specifies an active ingredient with a “molecular weight of about 5 to 9 kilodaltons.” … The term might refer to the weight of the most numerous molecule, it might refer to weight as calculated by the average weight of all molecules, or it might refer to weight as calculated by an average in which heavier molecules count for more. The claim, Sandoz argues, does not tell us which way we should calculate weight.

To illustrate, imagine we have a sample of copolymer-1 (the active ingredient) made up of 10 molecules: 4 weigh 6 kilodaltons each, 3 weigh 8 kilodaltons each, and 3 weigh 9 kilodaltons each. Using the first method of calculation, the “molecular weight” would be 6 kilodaltons, the weight of the most prevalent molecule. Using the second method, the molecular weight would be 7.5 (total weight, 75, divided by the number of molecules, 10). Using the third method, the molecular weight would be more than 8, depending upon how much extra weight we gave to the heavier molecules.

Teva argued in the District Court that the term “molecular weight” in the patent meant molecular weight calculated in the first way (the weight of the most prevalent molecule, or peak average molecular weight). Sandoz, however, argued that figure 1 of the patent showed that Teva could not be right. (We have set forth figure 1 in the Appendix, below). That figure, said Sandoz, helped to show that the patent term did not refer to the first method of calculation. Figure 1 shows how the weights of a sample’s molecules were distributed in three different samples. The
curves indicate the number of molecules of each weight that were present in each of the three. For example, the figure’s legend says that the first sample’s “molecular weight” is 7.7. According to Teva, that should mean that molecules weighing 7.7 kilodaltons were the most prevalent molecules in the sample. But, look at the curve, said Sandoz. It shows that the most prevalent molecule weighed not 7.7 kilodaltons, but slightly less than 7.7 (about 6.8) kilodaltons. After all, the peak of the first molecular weight distribution curve (the solid curve in the figure) is not at precisely 7.7 kilodaltons, but at a point just before 7.7. Thus, argued Sandoz, the figure shows that the patent claim term “molecular weight” did not mean molecular weight calculated by the first method. It must mean something else. It is indefinite.

The District Court did not accept Sandoz’s argument. Teva’s expert testified that a skilled artisan would understand that converting data from a chromatogram to molecular weight distribution curves like those in figure 1 would cause the peak on each curve to shift slightly; this could explain the difference between the value indicated by the peak of the curve (about 6.8) and the value in the figure’s legend (7.7). Sandoz’s expert testified that no such shift would occur. The District Court credited Teva’s expert’s account, thereby rejecting Sandoz’s expert’s explanation. The District Court’s finding about this matter was a factual finding—about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights. Based on that factual finding, the District Court reached the legal conclusion that figure 1 did not undermine Teva’s argument that molecular weight referred to the first method of calculation (peak average molecular weight).

When the Federal Circuit reviewed the District Court’s decision, it recognized that the peak of the curve did not match the 7.7 kilodaltons listed in the legend of figure 1. But the Federal Circuit did not accept Teva’s expert’s explanation as to how a skilled artisan would expect the peaks of the curves to shift. And it failed to accept that explanation without finding that the District Court’s contrary determination was “clearly erroneous.” The Federal Circuit should have accepted the District Court’s finding unless it was “clearly erroneous.” Our holding today makes clear that, in failing to do so, the Federal Circuit was wrong.

Appendix to opinion of the Court

APPENDIX

![Graph]

FIG. 1 (with minor additions to emphasize that the peak of the solid curve does not correspond precisely to 7.7 kDa)
In re Packard

751 F.3d 1307 (Fed. Cir. 2014)

Per Curiam

This case raises an important question: what standard for indefiniteness should the PTO apply to pre-issuance claims? The parties point to no case in which we previously have addressed this question.

The Patent Trial and Appeal Board (“Board”) held Mr. Packard’s applied-for patent claims indefinite, and therefore not in compliance with the statutory drafting requirements of 35 U.S.C. § 112(b) … . Mr. Packard, on appeal to this court, insists that the Board misapplied the standard of indefiniteness by finding his claims indefinite on grounds that they “contain[] words or phrases whose meaning is unclear.” He believes that, had the Board applied an “insolubly ambiguous” standard[†] to his claims, those claims would not have been held indefinite.

For the reasons we shall explain, we affirm the Board’s rejection of Mr. Packard’s claims.

Background

The application in this appeal covers a coin change holder. The coin holder is a thin plastic card that has four different channels on its front surface for storing different types of coins, as shown in the patent figures reproduced below.

Figure 1 shows a frontal view of the card and Figure 2 shows a cross-section of the card.

The examiner rejected Mr. Packard’s original application on three grounds: lack of adequate written description, claim indefiniteness, and obviousness. Following this rejection, Mr. Packard cancelled all of his original claims and substituted a new set of claims numbered 28 through 37.

Claims 28 through 37 are at issue in this appeal, of which claims 28, 29 and 34 are representative:

28. I claim a small, thin, flat plane, rectangular change holding card and wallet/billfold or purse construction with the front top side of the card comprising three raised, straight, parallel, double flanged separators and two raised, straight, parallel, double flanged side edges and a raised side edge end thereby forming four parallel, side by side, flanged

[†] [Ed. Note: The Federal Circuit issued this decision on May 6, 2014, eight days after the Supreme Court heard argument in the Nautilus case (on April 28, 2014). The Supreme Court issued its decision in Nautilus about a month after Packard, on June 2, 2014.]
coin holding channels or rows of the same length and of different widths, one for quarters, one for dimes, one for nickels, and one for pennies, that are similarly blocked at one side edge by the raised side end edge with the other side of the channel/rows open except for small, fixed, flexible, partially moveable, rubber or plastic retainers that are attached to the topside and ends of the double flanged separators such that coins can be retained on the card and yet slide freely above the surface of the card and obliquely overlap as necessary within the channel/rows between the separators while the bottom, back side of the card is constructed with a wallet, billfold or purse extending from it.

29. The change holding card wallet, billfold, purse of claim 28, wherein the change holding card is constructed as part of the wallet, billfold, or purse and affixed to a surface and contained within the wallet, billfold or purse.

34. I claim a small thin uniformly flat plane rectangular coin holding card comprising side edge retainers, a closed side retainer, small inclined/sloped end protrusions, multiple raised parallel, straight and double flanged channel/row separators, small flexible protruding retainers on the top side ends of the channel/row separators, all of which are arranged on the upper surface of the card such that a various denomination of coins can be held and retained on the card within a respective channel/row and can slide freely within the double flanges and slightly above the flat surface of the card and can also be stored obliquely partially overlapping.

The examiner, in his final rejection, again found the pending claims invalid on the same three grounds: claims 28-33 and 37 for lack of written description, claims 28-37 for indefiniteness, and claims 28-37 for obviousness. … Regarding indefiniteness, the examiner pointed out that several claim limitations failed to meet the requirements of 35 U.S.C. § 112(b) because they lacked an antecedent basis or were otherwise unclear.

Mr. Packard appealed the examiner’s final rejection to the Board … . In the course of affirming the examiner’s indefiniteness rejection, the Board applied the review standard set forth in the Manual of Patent Examining Procedure (“MPEP”) § 2173.05(e), namely, “[a] claim is indefinite when it contains words or phrases whose meaning is unclear.” On rehearing, the Board declined to modify its decision.

Mr. Packard appeals the Board’s decision. In its response to Mr. Packard’s opening brief on appeal, the PTO focused on the indefiniteness issue … .

... Discussion

1.

Petitioner Packard … contends that the “insolubly ambiguous” standard of this court for indefiniteness is mandated not only for our use in deciding cases in which the patent has already issued and is being challenged (“post-issuance cases”), but also for cases in which no patent has yet issued and in which the applied-for claims
are being evaluated by the PTO ("pre-issuance cases"). He states that this standard is more favorable to his case than the standard applied to his claims by the PTO.

For the reasons we shall explain, we ... conclude that, when the PTO has initially issued a well-grounded rejection that identifies ways in which language in a claim is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention, and thereafter the applicant fails to provide a satisfactory response, the PTO can properly reject the claim as failing to meet the statutory requirements of § 112(b). The satisfactory response by the applicant can take the form of a modification of the language identified as unclear, a separate definition of the unclear language, or, in an appropriate case, a persuasive explanation for the record of why the language at issue is not actually unclear. On the facts before us, this holding suffices to uphold the rejection that occurred here.

2. The grounds for this holding derive from a combination of the PTO’s examination function under 35 U.S.C. § 131 et seq. and the substantive standard of 35 U.S.C. § 112(b). Congress assigned to the PTO the responsibility to examine applications to ensure compliance with the statutory criteria for issuance of a patent. 35 U.S.C. § 131. In the PTO, an applicant’s “claim is, or is supposed to be, examined, scrutinized, limited, and made to conform to what he is entitled to.” Keystone Bridge Co. v. Phoenix Iron Co., 95 U.S. 274, 278 (1877).

Congress also provided for examination to be an interactive process, which it commonly is. One or more rejections or objections by an examiner based on identified problems are followed by one or more responses from the applicant that address the identified problems, whether by revising claims or by furnishing information and explanation that shows why the initially perceived problems are not problems after all. 35 U.S.C. § 132; see also §§ 133, 134. The examination system regularly involves substantive interaction with applicants, relying on their distinctive incentives and abilities to enhance understanding and to help the PTO ensure compliance with statutory standards.2

The PTO must be able to make the congressionally created examination process work so that it fulfills its purpose of producing patents whose claims meet the statutory standards. We earlier approved a procedural mechanism for the PTO to use in doing this, which we refer to as the “prima facie case.” See In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1984). “In the prosecution of a patent, the initial burden falls on the PTO [examiner] to set forth the basis for any rejection.” Hyatt v. Dudas, 492 F.3d 1365, 1369-70 (Fed. Cir. 2007). The PTO thus meets its obligation to explain adequately the shortcomings it perceives so that the applicant is properly notified

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2 See, e.g., Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1284 (Fed. Cir. 2005) (upholding examiner demand, under 37 C.F.R. § 1.105, for “information that the applicant is in the best position to most cheaply provide”); see also PTO, Notice of Public Hearing and Request for Comments on Issues Related to the Identification of Prior Art During the Examination of a Patent Application, 64 Fed. Reg. 28803, 28805 (1999) (stressing that “inventors are generally in the best position to be aware of the state of the art”).
and able to respond. “Once the applicant is so notified, the burden shifts to the applicant to rebut the prima facie case with evidence and/or argument.” Id.

The “prima facie case” determination is a purely procedural device that operates at the examiner level to clarify how the interaction process proceeds. Thereafter any final rejection by the examiner, and any review of the rejection, whether by the Board or through appeal to the courts, turns on the substantive question of the merits of the rejection. Piasecki, 745 F.2d at 1472 (citing In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976) (“When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. *** An earlier decision should not, as it was here, be considered as set in concrete, and applicant’s rebuttal evidence then be evaluated only on its knockdown ability. *** [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached.”)); see also In re Jung, 637 F.3d 1356, 1362 (Fed. Cir. 2011).

The same approach to making the examination process work is an appropriate one for addressing the question of indefiniteness. We have elsewhere noted that indefiniteness rejections by the PTO arise in a different posture from that of indefiniteness challenges to an issued patent. See Exxon Research & Eng’g v. United States, 265 F.3d 1370, 1380 (Fed. Cir. 2001). It makes good sense, for definiteness and clarity as for other validity requirements, for the PTO initially to reject claims based on a well-founded prima facie case of lack of clarity (in its several forms) based on the perspective of one of ordinary skill in the art in view of the entire written description and developing prosecution history. Then, if the applicant does not adequately respond to that prima facie case, to confirm that rejection on the substantive basis of having failed to meet the requirements of § 112(b). Furthermore, we can reach that conclusion and decide the present case without regard to the proper formulation of the judicially-applied indefiniteness standard that may be appropriate for post-issuance assessment of indefiniteness, a matter currently under review by the Supreme Court. See Nautilus, Inc. v. Biosig Instruments, Inc., cert. granted, 82 U.S.L.W. 3195 (U.S. Jan. 10, 2014) (No. 13-369).

As the statutory language of “particular[ity]” and “distinct[ness]” indicates, claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms. It is the claims that notify the public of what is within the protections of the patent, and what is not. See, e.g., Merrill v. Yeomans, 94 U.S. 568, 573-74 (1876); United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942).

At the same time, this requirement is not a demand for unreasonable precision. The requirement, applied to the real world of modern technology, does not contemplate in every case a verbal precision of the kind found in mathematics. Nor could it do so in a patent system that actually works, in practice, to provide effective protection for modern-day inventions. Rather, how much clarity is required necessarily invokes some standard of reasonable precision in the use of language in the context of the circumstances. See Georgia-Pacific Corp. v. U.S. Plywood Corp., 258 F.2d 124, 136 (2d Cir. 1958) (“[P]atentable inventions cannot always be described in terms of exact measurements, symbols and formulae, and the applicant necessarily must use the meager tools provided by language, tools which admittedly lack exacti-
tude and precision. If the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.

The PTO, in examining an application, is obliged to test the claims for reasonable precision according to these principles. We have recognized the importance of the role that the PTO can play in ensuring that patent claims are clear and unambiguous. For example, in *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989), a patent interference case, the court said:

> during patent prosecution … claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. *** An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

Recently, in *Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008) (affirming the district court’s finding that the term “fragile gel” was indefinite), the court said:

> We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.

3.

Given the role of the applicant in the process, it is a reasonable implementation of the examination responsibility, as applied to § 112(b), for the PTO, upon providing the applicant a well-grounded identification of clarity problems, to demand persuasive responses on pain of rejection. That approach decides this case, because Mr. Packard did not offer a satisfactory response to well-grounded indefiniteness rejections in this case. The examiner here, having ample grounds, set forth a variety of ways in which he found the claims imprecise or confusing, sometimes not even understandable, considering them in light of the written description.

Mr. Packard did not respond adequately to this group of claim language problems. He ignored some entirely. As to others, he offered brief explanations of what he thought certain material in the written description and figures showed. But he did not focus on the claim language difficulties, nor did he propose clarifying changes or show why, on close scrutiny, the existing claim language really was as reasonably precise as the circumstances permitted.

The Board relied on this failure of response to the examiner’s well-grounded rejections in affirming on the merits the examiner’s final rejection. The Board reviewed and agreed with the examiner’s identification of the indefiniteness problems that constituted Mr. Packard’s failure to adequately comply with the statutory requirements of § 112(b), and for which there had been no satisfactory response from Mr. Packard. On reconsideration, the Board stood by its affirmance of the rejection,
noting the crucial distinction between what Mr. Packard argued and what is required to address an indefiniteness problem: Mr. Packard’s “arguments focus on what is contained in the disclosure, whereas the indefiniteness to which [§ 112(b)] is applied is in the language of the claims.”

In some cases it is difficult enough for courts to construe claims when the draftsperson has made every effort to be clear and concise, let alone when the claims have readily observable ambiguities or incoherencies within them. Because Mr. Packard had an opportunity to bring clarity to his claim language, we affirm the Board’s findings as to indefiniteness under the MPEP standard properly applied by the PTO, the standard which we have here approved.

... PacingTechs., LLC v. Garmin Int’l, Inc. 778 F.3d 1021 (Fed. Cir. 2015)

Moore, Judge:

Pacing Technologies appeals from the district court’s grant of summary judgment that Garmin International’s accused products do not infringe the asserted claims of Pacing’s U.S. Patent No. 8,101,843. We affirm.

Background

The ’843 patent is directed to methods and systems for pacing users during activities that involve repeated motions, such as running, cycling, and swimming. The preferred embodiment of the ’843 patent describes a method for aiding a user’s pacing by providing the user with a tempo (for example, the beat of a song or flashes of light) corresponding to the user’s desired pace.

Pacing alleges that Garmin GPS fitness watches and microcomputers used by runners and bikers infringe the ’843 patent. The Garmin Connect website allows users to design and transfer workouts to the Garmin devices. Workouts consist of a series of intervals to which the user can assign a duration and target pace value. The devices display the intervals of a particular workout during operation, for example, by counting down the time for which the user intends to maintain a particular pace. The devices may also display the user’s actual pace, e.g., 50 to 70 spm, or steps per minute. The devices do not play music or output a beat corresponding to the user’s desired or actual pace.

Claim 25 of the ’843 patent, the only asserted independent claim, reads as follows (emphases added):

A repetitive motion pacing system for pacing a user comprising:

- a web site adapted to allowing the user to pre-select from a set of user-selectable activity types an activity they wish to perform and entering one or more target tempo or target pace values corresponding to the activity;
- a data storage and playback device; and
- a communications device adapted to transferring data related to the pre-selected activity or the target tempo or the target pace values between the web site and the data storage and playback device.
The district court construed the term “playback device” as “a device capable of playing audio, video, or a visible signal.” The district court also held that the preamble to claim 25 is a limitation and construed it to mean “a system for providing a sensible output for setting the pace or rate of movement of a user in performing a repetitive motion activity.” This construction did not address whether the repetitive motion pacing system was required to play back the pace information using a tempo.

Garmin moved for summary judgment of noninfringement, contending that the accused devices are not “playback devices” under the district court’s construction. Pacing argued that the accused devices are “playback devices” because they “play” workout information to the user, which can include the user’s target and actual pace. To resolve this dispute, the district court supplemented its construction of “playback device” in the summary judgment order, holding that “[t]o be a playback device as envisioned in the patent, the device must play back the pace information.” The court relied on the use of the term in the context of the specification and on its earlier decision that the preamble to claim 25 is limiting. The court granted summary judgment of noninfringement to Garmin, reasoning that while “[t]he [ac]cused devices repeat back or display the pace input or selections,” they “do not ‘play’ the target tempo or pace information *** as audio, video, or visible signals.” Both parties characterize the court’s construction of the term “playback device” as implicitly requiring the devices to play the pace information as a metronomic tempo, as described in the preferred embodiment of the ’843 patent. …

Discussion

“[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specification[]], along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law, and the Court of Appeals will review that construction de novo.” Teva Pharm. USA Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015). Because the only evidence at issue on appeal and presented to the district court in this claim construction was intrinsic, our review of the constructions is de novo. We review a grant of summary judgment from a court in the Ninth Circuit de novo. Genentech, Inc. v. Amgen, Inc., 289 F.3d 761, 767 (Fed. Cir. 2002).

I. Claim Construction

On appeal, the parties dispute whether the asserted claims require the claimed devices to play back the pace information using a tempo, such as the beat of a song or flashes of light. This dispute turns on whether the preamble to claim 25 is limiting and on the construction of a “repetitive motion pacing system” as recited in the preamble.

We hold that the preamble to claim 25, which reads “[a] repetitive motion pacing system for pacing a user ***,” is limiting. “Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim.” Bicon, Inc. v. Straumann Co., 441 F.3d 945, 952 (Fed. Cir. 2006). However, “[w]hen limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary com-
ponent of the claimed invention.” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003).

That is the case here. The term “user” in the preamble of claim 25 provides antecedent basis for the term “user” in the body of that claim. The body of claim 25 recites “a web site adapted to allowing the user to preselect from a set of user-selectable activity types an activity they wish to perform and entering one or more target tempo or target pace values corresponding to the activity.” (Emphasis added). The term “repetitive motion pacing system” in the preamble of claim 25 similarly provides antecedent basis for the term “repetitive motion pacing system” recited as a positive limitation in the body of claim 28, which depends from claim 25. Claim 28 of the ’843 patent reads: “[t]he repetitive motion pacing system of claim 25, wherein the repetitive motion pacing system can determine a geographic location of the data storage and playback device.” Because the preamble terms “user” and “repetitive motion pacing system” provide antecedent basis for and are necessary to understand positive limitations in the body of claims in the ’843 patent, we hold that the preamble to claim 25 is limiting.

The plain and ordinary meaning of the phrase “repetitive motion pacing system for pacing a user” does not require the claimed system to pace the user by playing back the pace information using a tempo. However, claim terms are construed in light of the specification and prosecution history, not in isolation. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The specification and prosecution history compel departure from the plain meaning in only two instances: lexicography and disavowal. *Thorner v. Sony Computer Entm’t*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). The standards for finding lexicography and disavowal are “exacting.” *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). To act as a lexicographer, a patentee must “clearly set forth a definition of the disputed claim term” and “clearly express an intent to define the term.” *Thorner*, 669 F.3d at 1365. Similarly, disavowal requires that “the specification [or prosecution history] make[] clear that the invention does not include a particular feature.” *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).

We have found disavowal or disclaimer based on clear and unmistakable statements by the patentee that limit the claims, such as “the present invention includes ***” or “the present invention is ***” or “all embodiments of the present invention are ***.” See, *e.g.*, *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013); *Honeywell Int’l, Inc. v. ITT Indus.*, Inc., 452 F.3d 1312, 1316-19 (Fed. Cir. 2006); *SciMed Life Sys., Inc.*, 242 F.3d at 1343-44. We have found disclaimer when the specification indicated that, for “successful manufacture,” a particular step was “require[d].” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1367 (Fed. Cir. 2007). We have found disclaimer when the specification indicated that the invention operated by “pushing (as opposed to pulling) forces,” and then characterized the “pushing forces” as “an important feature of the present invention.” *SafeTCare Mfg. v. Tele-Made, Inc.*, 497 F.3d 1262, 1269-70 (Fed. Cir. 2007). We also have found disclaimer when the patent repeatedly disparaged an embodiment as “antiquated,” having “inherent inadequacies,” and then detailed the
“deficiencies [that] make it difficult” to use. *Chi. Bd. Options Exch., Inc. v. Int’l Sec. Exch.*, 677 F.3d 1361, 1372 (Fed. Cir. 2012). Likewise, we have used disclaimer to limit a claim element to a feature of the preferred embodiment when the specification described that feature as a “very important feature *** in an aspect of the present invention,” and disparaged alternatives to that feature. *Inpro II Licensing, S.A.R.L. v. T-Mobile USA Inc.*, 450 F.3d 1350, 1354-55 (Fed. Cir. 2008). When a patentee “describes the features of the ‘present invention’ as a whole,” he alerts the reader that “this description limits the scope of the invention.” *AGA Med. Corp.*, 717 F.3d at 936.

Here, the specification similarly contains a clear and unmistakable statement of disavowal or disclaimer. In a section entitled “Summary and Objects of the Invention,” the ’843 patent states that “it is a principal object of the present invention to provide a computer-implemented, network-based system having a networked server, database, client computer, and input/output device for use by individuals engaged in repetitive motion activities *** .” It then lists 18 additional features, each time preceding the feature with the phrase “[i]t is another object of the present invention” or “[i]t is still another object of the present invention.” This is a common practice in patent drafting. Many times, the patent drafter will cast certain features as “an object of the present invention,” and often those “objects of the present invention” correspond to features recited in the claims. That is the case here, as many of the different “objects of the present invention” disclosed in the ’843 patent are recited as features in one or more independent or dependent claims. The characterization of a feature as “an object” or “another object,” or even as a “principal object,” will not always rise to the level of disclaimer. In this case, where the patent includes a long list of different “objects of the present invention” that correspond to features positively recited in one or more claims, it seems unlikely that the inventor intended for each claim to be limited to all of the many objects of the invention. However, the ’843 patent goes further, and includes additional language that constitutes unmistakable disclaimer when considered in the context of the patent as a whole. Immediately following the enumeration of the different objects of the present invention, the ’843 patent states that “[t]hose [listed 19 objects] and other objects and features of the present invention are accomplished, as embodied and fully described herein, by a repetitive motion pacing system that includes *** a data storage and playback device adapted to producing the sensible tempo.” With these words, the patentee does not describe yet another object of the invention—he alerts the reader that the invention accomplishes all of its objects and features (the enumerated 19 and all others) with a repetitive motion pacing system that includes a data storage and playback device adapted to produce a sensible tempo. In the context of this patent, this clearly and unmistakably limits the “present invention” to a repetitive motion pacing system having a data storage and playback device that is adapted to producing a sensible tempo.

Pacing argues that a “repetitive motion pacing system for pacing a user” cannot be limited to devices that produce a sensible tempo because the ’843 patent discloses an embodiment of a repetitive motion pacing system where the playback device does not need to produce a sensible tempo. Pacing points to the specification’s de-
scription of a repetitive motion pacing system having a playback device that plays video landscapes to a user who is, for example, running on a treadmill, with the video “automatically calibrated to match the speed of the user’s pace,” to simulate the user running through the actual landscape. Pacing argues that if the claim is construed to limit the invention to a repetitive motion pacing device adapted to producing a sensible tempo, this particular embodiment will not be covered. Pacing argues that for this reason, we should reject the construction.

We disagree for two reasons. First, it is not clear that our construction excludes this embodiment. Our construction requires the repetitive motion pacing system to produce a sensible tempo, but it does not exclude additional features, such as outputting video matching a user’s pace. Moreover, the description of the embodiment that Pacing points to does not, as Pacing argues, exclude the production of a sensible tempo as required by the construction. Just because an embodiment does not expressly disclose a feature does not mean that embodiment excludes that feature. Second, even if Pacing is correct that this embodiment does not play a sensible tempo and therefore would be excluded under our construction, this is not a reason to ignore the specification’s clear and unmistakable disavowal. It is true that constructions that exclude the preferred embodiment are disfavored. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). However, in a case such as this, where the patent describes multiple embodiments, every claim does not need to cover every embodiment. See Aug. Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278, 1285 (Fed. Cir. 2011). This is particularly true where the plain language of a limitation of the claim does not appear to cover that embodiment. The preamble of claim 25 differs from the preambles of the other seven independent claims. Claim 25 requires a “repetitive motion pacing system for pacing a user.” The plain language requires the system to pace the user. We conclude that the system of claim 25 must be capable of producing a sensible tempo for pacing the user.

II. Infringement

We hold that there is no genuine dispute of material fact as to whether the Garmin devices produce a sensible tempo. Merely displaying the rate of a user’s pace—for example, displaying “100 steps per minute”—does not produce a sensible tempo. Garmin’s accused devices are therefore not repetitive motion pacing devices. We affirm the district court’s grant of summary judgment of noninfringement of the ’843 patent.

Triton Tech v. Nintendo

753 F.3d 1375 (Fed. Cir. 2014)

Moore, Judge:

Triton Tech appeals from the district court’s judgment that the means-plus-function term “integrator means” renders the asserted claims of Triton’s U.S. Patent No. 5,181,181 invalid for indefiniteness. We affirm.

Background

Triton sued Nintendo, alleging that the Wii Remote used in combination with a related accessory infringes the ’181 patent. The ’181 patent is directed to an input device for a computer. It discloses that a user can communicate with a computer by
moving the input device—much like using a mouse, but in three dimensions. Col. 2, ll. 50-67. The input device sends commands to the computer based on the input device’s three-dimensional position, attitude (i.e., orientation), and motion. Abstract. For example, a user may be able to manipulate an object that is represented graphically on the computer by moving the input device in a manner in which the user wishes to manipulate the object. Col. 1, ll. 15-22.

The input device includes components for determining its position, attitude, and motion. In the preferred embodiment, these components include three accelerometers and three rotational rate sensors for measuring linear acceleration along, and rotational velocity about, three orthogonal axes. Col. 3, ll. 3-29, Fig. 1(d). The preferred embodiment also includes a conventional microprocessor that is programmed to periodically read and numerically integrate over time digitized acceleration and rotational rate values to calculate the position, attitude, and motion values for the input device. Col. 7, ll. 15-25. The ’181 patent does not further explain how the numerical integration is performed, only that it is performed in a “conventional manner.” Col. 10, ll. 7-9. The input device then outputs these values to the computer to facilitate the user’s interaction with the computer. Col. 11, ll. 14-42.

Claim 4 is representative of the asserted claims:

An input device for providing information to a computing device, comprising: ***

a first acceleration sensor ***; a second acceleration sensor ***; a third acceleration sensor [each producing analog acceleration sensor signals];

a first rotational rate sensor ***; a second rotational rate sensor ***; a third rotational rate sensor ***;

an analog-to-digital converter associated with said input device which quantizes said analog acceleration sensor signals to produce digital acceleration sensor values;

a first-in, first-out buffer memory which temporarily stores said digital acceleration sensor values from said analog-to-digital converter in sequential order for later processing;

integrator means associated with said input device for integrating said acceleration signals over time to produce velocity signals for linear translation along each of *** first, second and third axes; and

communication means associated with said input device for communicating information between said input device and said computing device.

(Emphases added).

Each asserted claim recites an “integrator means.” The district court held that this term rendered the asserted claims indefinite. It determined that the corresponding structure for performing the recited integrating function was a “conventional microprocessor having a suitably programmed read-only memory.” [Claim Construction Order (“CCO”) at 14. It found that the ’181 patent did not disclose any algorithm for performing the recited integrating function. Id. at 15-16. It noted that the ’181 patent broadly discloses using “numerical integration,” but deter-
mined that this alone was not a sufficient disclosure because “‘[n]umerical integration’ *** is not a single algorithm, but rather a whole class of algorithms that can be used to calculate definite integrals *** .” Id. at 16. The district court thus concluded that the asserted claims were indefinite. Id. at 15-16 (citing Aristocrat Techs. Austr. Pty Ltd. v. Int’l Gaming Tech., 521 F.3d 1328, 1334 (Fed. Cir. 2008)). Triton appeals. …

Discussion

... Section 112 ¶ 6 allows a patentee to express an element of a claim as a means for performing a specific function. 35 U.S.C. § 112 ¶ 6 (2006). In exchange for using this form of claiming, the patent specification must disclose with sufficient particularity the corresponding structure for performing the claimed function and clearly link that structure to the function. Ibsormeith IP, LLC v. Mercedes-Benz USA, LLC, 732 F.3d 1376, 1379 (Fed. Cir. 2013). If the function is performed by a general purpose computer or microprocessor, then the specification must also disclose the algorithm that the computer performs to accomplish that function. Aristocrat, 521 F.3d at 1333. Failure to disclose the corresponding algorithm for a computer-implemented means-plus-function term renders the claim indefinite. Ergo Licensing LLC v. CareFusion 303, Inc., 673 F.3d 1361, 1363 (Fed. Cir. 2012).

Triton concedes that the structure corresponding to “integrator means” is a conventional microprocessor, and contends that the ’181 patent discloses an algorithm for performing the integrating function with enough specificity to render the claims discernible to a person of ordinary skill. First, Triton argues that merely using the phrase “numerical integration” is sufficient disclosure of an algorithm because numerical integration was well known to those skilled in the art. Second, Triton argues that the ’181 patent discloses a two-step algorithm for accomplishing the integrating function: (1) sampling measured values over time and (2) accumulating by continuously summing areas defined by the sampled values. Triton asserts that the ’181 patent discloses the sampling step as acquiring instantaneous values from the different sensors, formatting them to digital values, and then storing them for further processing. Appellant’s Br. 20-21 (citing ’181 patent, col. 3, ll. 30-38; col. 9, ll. 2-6, 28-37, 49-59). Triton contends that the ’181 patent discloses the accumulating step as “clearing all numeric integration accumulators” and continually performing numerical integration to compute the position and attitude values. Id. at 21-22 (citing ’181 patent, col. 7, l. 65 – col. 8, l. 3; col. 10, ll. 51-62; col. 7, ll. 21-36; col. 8 ll. 11-12).

We affirm the district court’s determination that the asserted claims of the ’181 patent are indefinite because the specification does not disclose an algorithm for performing the claimed integrating function of the “integrator means.” It is certainly true that an algorithm can be expressed in many forms, including flow charts, a series of specific steps, mathematical formula, prose, and so on. Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1340 (Fed. Cir. 2008). However, merely using the term “numerical integration” does not disclose an algorithm—i.e., a step-by-step procedure—for performing the claimed function. Ergo Licensing, 673 F.3d at 1365 (“Even described in prose, an algorithm is still a step-by-step procedure for accom-
lishing a given result.”). As the district court correctly determined, numerical integration is not an algorithm but is instead an entire class of different possible algorithms used to perform integration. CCO at 16. Disclosing the broad class of “numerical integration” does not limit the scope of the claim to the “corresponding structure, material, or acts” that perform the function, as required by § 112. Indeed, it is hardly more than a restatement of the integrating function itself. Disclosure of a class of algorithms “that places no limitations on how values are calculated, combined, or weighted is insufficient to make the bounds of the claims understandable.” Iborneith, 732 F.3d at 1382.

The fact that various numerical integration algorithms may have been known to one of ordinary skill in the art does not rescue the claims. “[A] bare statement that known techniques or methods can be used does not disclose structure.” Biomedino, LLC v. Waters Techs. Corp., 490 F.3d 946, 953 (Fed. Cir. 2007); see also ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 519 (Fed. Cir. 2012). The district court correctly recognized that “[a]lthough a person of skill in the art might be able to choose an appropriate numerical integration algorithm and program it onto a microprocessor, the [p]atent discloses no algorithm at all.” CCO at 16. We thus conclude that the district court correctly found that the ’181 patent’s disclosure of “numerical integration” does not satisfy the disclosure requirement of § 112 ¶ 6; “numerical integration” is not an algorithm.

We hold that Triton has waived its second argument that the ’181 patent discloses a two-step algorithm that consists of sampling and accumulating. Triton did not make this argument to the district court. Instead, it argued that the corresponding structure for “integrator means” is a conventional microprocessor “that performs integration.” Plaintiff’s Opening Claim Construction Brief at 14. It explained that “[t]he position, velocity, and attitude values are computed and numerically integrated in a ‘known manner,’” and that “[n]umerical integration describes the ways in which a numerical value is reached from the integration of definite integrals.” Plaintiff’s Reply Claim Construction Brief at 7. It did not argue that the ’181 patent discloses a two-step numerical algorithm. It argued only that the term “numerical integration” was sufficient.

To the extent that Triton now argues that one of skill in the art would have understood the bare disclosure of “numerical integration” as disclosing a particular two-step algorithm, we find that it also waived that argument. Triton argued to the district court that “numerical integration describes the ways in which a numerical value is reached from *** integration,” that “the method of numerical integration would [have been] obvious” and that the specification disclosed “numerical integration” such that “one of ordinary skill in the art could identify a preferred mathematical equation with which to perform the function of integrating.” Id. at 7-8. Thus, at best, Triton argued to the district court that one of skill in the art would have been able to identify a preferred integration algorithm because different methods for performing numerical integration were well known. Triton did not argue below that one of skill in the art would have understood the disclosure of “numerical integration” as describing a particular two-step algorithm. It cannot make that argument for the first time on appeal.
In exchange for expressing “integrator means” as a means-plus-function term, Triton was required to disclose an algorithm for performing the claimed integrating function. Because it did not do so, the asserted claims are indefinite.

...  

EON Corp. IP Holdings v. AT&T Mobility

_ F.3d _ (Fed. Cir. 2015)

Prost, Chief Judge:

In these consolidated cases, EON Corp. IP Holdings asserts U.S. Patent No. 5,663,757 against a number of defendants. The district court granted the defendants’ motion for summary judgment, holding all claims of the ’757 patent invalid as indefinite. In particular, the district court found that the specification failed to disclose an algorithm to provide structure for various computer-implemented means-plus-function elements. On appeal, we affirm.

I. Background

The asserted ’757 patent, which issued on September 2, 1997, is directed to software embodied in a “local subscriber data processing station” that operates in tandem with a television to interconnect various interactive features of the television. The software allows actions such as “impulse purchase transactions with immediate payment,” audience participation voting, and sorting television programs by theme. EON alleges that “the modern iteration of the ’757 patent’s local subscriber data processing station is a smartphone with certain capabilities.”

Consequently, on September 23, 2010, EON filed an action against seventeen defendants, including smartphone manufacturers, cellular network providers, and smartphone content providers (“the FLO TV case”). Nine months later, on June 14, 2011, EON sued several other defendants in a separate action (“the AT&T case”). The two cases were consolidated through claim construction.

At the same time, the ’757 patent went through two reexaminations. The claims were amended in the first reexamination, and all claims as amended were confirmed in the second reexamination. However, on November 1, 2013, the defendants in the FLO TV action moved for summary judgment of invalidity for indefiniteness. To resolve the motion, the district court held a claim construction hearing … , a summary judgment hearing … , and a hearing to receive expert testimony … . Soon after the hearings, the district court granted summary judgment to the FLO TV defendants, finding that all claims of the ’757 patent were invalid as indefinite. The eight terms that were held to be indefinite are the following:

1. “means under control of said replaceable software means for indicating acknowledging shipment of an order from a remote station” (Claim 7);
2. “means controlled by replaceable software means operable with said operation control system for *** reconfiguring the operating modes by adding or changing features and introducing new menus” (Claims 1-6, 8-10);
3. “means responsive to said self contained software for establishing a mode of operations for selection of one of a plurality of authorized television program channels” (Claim 8);
4. “means establishing a first menu directed to different interactively selectable program theme subsets available from said authorized television program channels” (Claim 8);

5. “means for causing selected themes to automatically display a second menu” (Claim 8);

6. “means controlled by replaceable software means operable with said operation control system for establishing and controlling a mode of operation that records historical operating data of the local subscriber’s data processing station” (Claim 9);

7. “means controlled by replaceable software means operable with said operation control system for establishing and controlling fiscal transactions with a further local station” (Claim 10); and

8. “means for establishing an accounting mode of operation for maintaining and reporting fiscal transactions incurred in the operation of the local subscriber’s data processing station” (Claim 10).

Following its summary judgment order, the district court entered final judgment of invalidity …

II. Discussion

We review the grant of summary judgment of indefiniteness de novo, applying the same standard used by the district court. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). … We review the district court’s ultimate conclusion of indefiniteness under 35 U.S.C. § 112 de novo. Eidos Display, LLC v. AU Optronics Corp., 779 F.3d 1360, 1364 (Fed. Cir. 2015). In this case, the district court made numerous detailed findings of fact. Because the indefiniteness inquiry here is intertwined with claim construction, see Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1379 (Fed. Cir. 1999) (“[A] court’s determination of the structure that corresponds to a particular means-plus-function limitation is indeed a matter of claim construction.”), we review these subsidiary factual determinations for clear error. Teva Pharm. v. Sandoz, Inc., 135 S. Ct. 831, 836 (2015); see also Fed. R. Civ. P. 52(a)(6) (“Findings of fact *** must not be set aside unless clearly erroneous ***.”).

The parties agree that the claim terms at issue are all means-plus-function terms governed by 35 U.S.C. § 112 ¶ 6.¹ … Means-plus-function claim limitations under § 112 ¶ 6 must satisfy the definiteness requirement of § 112 ¶ 2. S3 Inc. v. NVIDIA Corp., 259 F.3d 1364, 1367 (Fed. Cir. 2001).

The parties also agree that the functions claimed in the terms at issue are all performed by computer software. It is well-established that the corresponding structure for a function performed by a software algorithm is the algorithm itself. See WMS Gaming, Inc. v. Int’l Game Tech., 184 F.3d 1339, 1348-49 (Fed. Cir. 1999).

¹ Paragraph 6 of 35 U.S.C. § 112 was replaced with newly designated § 112(f) when § 4(c) of the America Invents Act (AIA), Pub. L. No. 112-29, took effect on September 16, 2012. Because the applications resulting in the patents at issue in this case were filed before that date, we will refer to the pre-AIA version of § 112.
Accordingly, “[i]n cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, this court has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor.” Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech., 521 F.3d 1328, 1333 (Fed. Cir. 2008).

A. The Katz Exception

In this case, EON does not dispute that the ’757 patent discloses no algorithms. It is uncontested that the only structure disclosed in the ’757 patent is a microprocessor. For this reason, EON relies on an exception to the algorithm rule created in In re Katz Interactive Call Processing Patent Litigation, 639 F.3d 1303 (Fed. Cir. 2011). Katz held that a standard microprocessor can serve as sufficient structure for “functions [that] can be achieved by any general purpose computer without special programming.” Katz, 639 F.3d at 1316. In Katz, claim terms involving basic “processing,” “receiving,” and “storing” functions were not necessarily indefinite because a general purpose computer need not “be specially programmed to perform the recited function.” Id. However, other claim terms involving conditionally coupling calls were indefinite because those functions required special programming and no algorithm was disclosed. Id. at 1315.

This court has since analyzed the “narrow” Katz exception once, finding that it did not apply. See Ergo Licensing, LLC v. CareFusion 303, Inc., 673 F.3d 1361, 1364 (Fed. Cir. 2012). A representative example of one of the means-plus-function terms at issue in Ergo follows:

programmable control means coupled with said adjusting means for controlling said adjusting means, said programmable control means having data fields describing metering properties of individual fluid flows.

U.S. Patent No. 5,507,412 claim 1. The Ergo court explained that “[i]t is only in the rare circumstances where any general-purpose computer without any special programming can perform the function that an algorithm need not be disclosed.” Id. at 1365. The court found that an algorithm was needed to lend sufficient structure to the terms at issue because “[t]he ‘control means’ at issue in this case cannot be performed by a general-purpose computer without any special programming. The function of ‘controlling the adjusting means’ requires more than merely plugging in a general-purpose computer.” Id.

EON asserts that the functions claimed in the ’757 patent do not involve “special programming”—and thus fall within the Katz exception—because they are relatively simple to implement. However, the Katz exception is not so broad. As we stated in Katz, a microprocessor can serve as structure for a computer-implemented function only where the claimed function is “coextensive” with a microprocessor itself. Katz, 639 F.3d at 1316. Examples of such coextensive functions are “receiving” data, “storing” data, and “processing” data—the only three functions on which the Katz court vacated the district court’s decision and remanded for the district court to determine whether disclosure of a microprocessor was sufficient.

Katz’s “special programming” language has its origins in WMS Gaming. As mentioned above, WMS Gaming held that the corresponding structure for a soft-
ware algorithm is the algorithm. In *WMS Gaming*, disclosure of a general purpose computer was insufficient because “[a] general purpose computer, or microprocessor, programmed to carry out an algorithm creates ‘a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.’” *WMS Gaming*, 184 F.3d at 1348 (quoting *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994) (en banc) (abrogated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), aff’d but criticized sub nom. *Bilski v. Kappos*, 561 U.S. 593 (2010))). …

… After *WMS Gaming*, a number of cases held means-plus-function claims indefinite for failure to disclose a sufficient algorithm. See, e.g., *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1385 (Fed. Cir. 2009); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1367 (Fed. Cir. 2008); *Finisar Corp. v. DirecTV Grp.*, 523 F.3d 1323, 1340-41 (Fed. Cir. 2008); *Aristocrat*, 521 F.3d at 1338. For the “processing,” “receiving,” and “storing” claim terms, *Katz* distinguished those cases using *WMS Gaming*’s vocabulary, which culminated in *Katz*’s “special programming” phrase:

Those cases involved specific functions that would need to be implemented by programming a general purpose computer to convert it into a special purpose computer capable of performing those specified functions. See, e.g., *Aristocrat*, 521 F.3d at 1333-34; *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1253 (Fed. Cir. 2005); *WMS Gaming*, 184 F.3d at 1349. By contrast, in the seven claims identified above, *Katz* has not claimed a specific function performed by a special purpose computer, but has simply recited the claimed functions of “processing,” “receiving,” and “storing.” Absent a possible narrower construction of the terms “processing,” “receiving,” and “storing,” discussed below, those functions can be achieved by any general purpose computer without special programming.

*Katz*, 639 F.3d at 1316.

Taken in context, then, “special programming” does not denote a level of complexity. On this point, the district court erred in holding that “special programming” does not encompass commercially available off-the-shelf software. To the contrary, and as originally described in *Katz*, “special programming” includes any functionality that is not “coextensive” with a microprocessor or general purpose computer. *Id.* In other words … the general purpose computer becomes a special purpose computer when loaded with the special programming, so a general purpose computer or microprocessor no longer lends sufficient structure to the claim. Therefore, as is plain from this review, the *Katz* exception is a necessary corollary to the general rule stated in *WMS Gaming* and further elaborated in *Aristocrat* and other later cases. A microprocessor or general purpose computer lends sufficient structure only to basic functions of a microprocessor. All other computer-implemented functions require disclosure of an algorithm.

… *WMS Gaming* and *Katz* are consistent with recent Supreme Court precedent, including *Nautilus, Inc. v. Biosig Instruments, Inc.*, which warned against “diminish[ing] the definiteness requirement’s public-notice function and foster[ing] the innovation-discouraging zone of uncertainty against which this Court has
warned.” 134 S. Ct. 2120, 2130 (2014). The disclosure of structure under § 112 ¶ 6 serves the “purpose of limiting the scope of the claim to the particular structure disclosed, together with equivalents.” Aristocrat, 521 F.3d at 1336. A general purpose computer is flexible—it can do anything it is programmed to do. Id. at 1333. Therefore, the disclosure of a general purpose computer or a microprocessor as corresponding structure for a software function does nothing to limit the scope of the claim and “avoid pure functional claiming.” Id. As such, when a patentee invokes means-plus-function claiming to recite a software function, it accedes to the reciprocal obligation of disclosing a sufficient algorithm as corresponding structure.

B. Role of the Person of Ordinary Skill in the Art

EON also argues that a microprocessor can serve as sufficient structure for a software function if a person of ordinary skill in the art could implement the software function. This argument is meritless. In fact, we have repeatedly and unequivocally rejected this argument: a person of ordinary skill in the art plays no role whatsoever in determining whether an algorithm must be disclosed as structure for a functional claim element. See Noah Sys. v. Intuit Inc., 675 F.3d 1302, 1313 (Fed. Cir. 2012); Blackboard, 574 F.3d at 1385; Aristocrat, 521 F.3d at 1337.

To elaborate, “our case law regarding special purpose computer-implemented means-plus-functions claims is divided into two distinct groups: First, cases in which the specification discloses no algorithm; and second, cases in which the specification does disclose an algorithm but a defendant contends that disclosure is inadequate.” Noah, 675 F.3d at 1313. Where the specification discloses no algorithm, the skilled artisan’s knowledge is irrelevant. Id. (citing Aristocrat, 521 F.3d at 1337). Where the specification discloses an algorithm that the accused infringer contends is inadequate, we judge the disclosure’s sufficiency based on the skilled artisan’s perspective. Id. (citing Aristocrat, 521 F.3d at 1337; AllVoice Computing PLC v. Nuance Commc’ns, Inc., 504 F.3d 1236, 1245 (Fed. Cir. 2007)). The parties agree that the ‘757 patent’s specification discloses no algorithms, so this case falls in the first category, in which the skilled artisan’s knowledge is irrelevant.

C. Application of the Algorithm Requirement to this Case

In light of the foregoing discussion, resolution of this case is straightforward. The district court made explicit factual findings, based on expert testimony, that each of the eight claim terms at issue recited complicated, customized computer software. We see no clear error in any of the district court’s factual findings, nor any error in the district court’s ultimate conclusion of indefiniteness.

Significantly, EON does not contend on appeal that the terms at issue recite functions that are coextensive with a microprocessor. EON also does not differentiate between any of the claim terms in its argument. In fact, EON cites to testimony from its expert that a person skilled in the art would need to consult algorithms outside the specification to implement the claimed functions. Similarly, based on expert testimony, the district court found that “special code would have to be written in order to accomplish the claimed functionality.” As discussed above, this finding proves more than is necessary, [inasmuch] as the defendants [need] only show by
clear and convincing evidence that the terms at issue do not recite basic functions of a microprocessor. Therefore, the ’757 patent’s disclosure of a microprocessor does not lend sufficient structure to the means-plus-function terms at issue, and the ’757 patent’s claims are indefinite.

...
Chapter 3: Written Disclosure

It is conventional in patent law to think of the patent document as the record of a bargain between an inventor, who discloses an invention, and the general public, which confers on the inventor an exclusion right as a reward for that disclosure. “The disclosure required by the Patent Act is ‘the quid pro quo of the right to exclude.’” J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 142 (2001) (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974)); see also Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002) (“Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.”).

The Patent Act, in § 112(a), establishes two core validity requirements that establish the terms of this bargain. (We’ve already discussed the claim definiteness requirement, which is set forth separately in § 112(b).) These requirements help us police the terms of the public’s bargain with the inventor, assuring that [1] we receive adequate consideration (this is the enablement requirement), and [2] we are dealing with the right party, i.e., the actual inventor (this is the written description requirement). These requirements go to the quality of the written disclosure and its fit with the claims it purports to justify, which is separate from the question whether the invention substantively merits the patent reward. (We scrutinize substantive merit with three other validity requirements—utility, novelty, and nonobviousness.) The third requirement in § 112(a), known as best mode, has become something of a sidelight given its demotion in the 2011 America Invents Act: failure to comply with this requirement is no longer a defense in an infringement case.

The cases in this chapter focus on enablement and written description.

Enablement


In re Hoffmann

558 Fed. Appx. 985 (Fed. Cir. 2014)

Per Curiam

Eugene Hoffmann and David Lund appeal the rejection of their application for a patent on a “[t]ropical hurricane control system.” The rejected claims describe a process for weakening a tropical storm by injecting a super coolant such as liquid nitrogen into the eye wall of the storm from airplanes. The examiner rejected the claims for lack of enablement, and the Patent Trial and Appeal Board affirmed. We agree with the Board’s decision and affirm.

Background

Hoffmann and Lund’s patent application, No. 11/504,474, describes a “method and system for diminishing the intensity of tropical cyclones by delivering super coolant from [an] aircraft into the eye wall of the tropical cyclone.” According to the specification, delivering “a sufficient quantity” of super coolant into the storm’s...
eye wall “breaks the forming or recently formed eye wall, which will cause the eye wall to implode.” Although the method has never been tested, the specification contains a set of “preliminary calculations” detailing the amount of super coolant and number of airplanes necessary to address an example storm of small size.

Independent claim 36 is representative of the claims:

A process for disrupting a formed or forming tropical cyclone eye wall or eye or center of lowest pressure comprising: Introduction of a super coolant chemical agent sprayed with force (the super coolant is stored in a vessel under pressure) and or released from pre-measured containers from an appropriate number of large aircraft to reduce the temperature within the eye wall (top to bottom at sea level), thereby circulating the super coolant throughout the eye wall by the centrifugal force of the eye wall, alternatively into the eye or center of lowest pressure to reduce the temperature in the eye or center of lowest pressure and the water beneath, thereby reducing the wind and storm surge of the eye wall or raising the pressure in the eye or center of lowest pressure and converting it back to a tropical rainstorm.

The examiner rejected the claims for failure to comply with the enablement requirement of 35 U.S.C. § 112(a). The examiner relied on three principal grounds for his conclusion on lack of enablement. First, he noted that the preliminary calculations contained several unexplained assumptions and mathematical errors. Second, the examiner noted that the specification itself acknowledged the need for experimentation to determine the amount of super coolant needed and the optimal time to strike. Finally, the examiner cited a variety of publications by weather scientists who expressed serious doubts about the viability of weather modification plans like Hoffmann and Lund’s. The examiner ultimately concluded that Hoffmann and Lund “failed to provide a disclosure of the invention which would enable one of ordinary skill in the art to make and/or use the invention without undue experimentation.”

The Board affirmed the examiner’s rejection after applying the eight factor analysis set forth by In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Hoffmann and Lund appeal. …

We review the Board’s decision on enablement de novo and its underlying factual findings for substantial evidence. See In re Gartside, 203
Miller's Patent Cases

F.3d 1305, 1315-16 (Fed. Cir. 2000); Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1369 (Fed. Cir. 1999).

Discussion

Section 112(a) of the patent statute requires that the specification of a patent describe “the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains *** to make and use the same.” 35 U.S.C. § 112(a). A specification is not enabling if a person of ordinary skill in the art would be unable to practice the invention without “undue experimentation.” Wands, 585 F.2d at 737. When rejecting a claim for lack of enablement, the initial burden is on the PTO to set forth “a reasonable explanation” of why it believes the specification is not enabling. In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). The burden then shifts to the applicant to provide “suitable proofs indicating that the specification is indeed enabling.” Id. at 1562.

We agree with the Board that the PTO has met its burden and that Hoffmann and Lund have failed to meet theirs. As an initial matter, the examiner’s findings are more than enough to constitute a “reasonable explanation” of the doubts regarding enablement. Id. at 1561. The “preliminary calculations” contain figures that are either inaccurate or incoherent, raising the possibility that a person of ordinary skill would need to correct those errors in order to practice the claimed method. The patent itself acknowledges a need for further experimentation to determine the necessary or optimal value of certain variables. And perhaps most significantly, the very efficacy of the method itself is subject to considerable doubt in the scientific community. These points are sufficient to meet the PTO’s burden.

Hoffmann and Lund, on the other hand, offer little to meet their burden to show that the specification is indeed enabling. Their primary argument is that the specification must be enabling because the government has secretly implemented their method and abated or redirected many hurricanes over the past several years. But they have no evidence to support this theory. All they have is a speculative inference of government use drawn from the fact that relatively few named storms have made landfall in the United States in recent years. Hoffmann and Lund also argue that the specification is enabling because it contains a table estimating the number of airplanes necessary to treat tropical storms of different sizes. But that is not enough information to enable a person of ordinary skill in the art to practice the method without undue experimentation.

... 

Automotive Techs. Int’l v. BMW of North America

501 F.3d 1274 (Fed. Cir. 2007)

Louie, Judge:

Automotive Technologies International, Inc. (“ATI”) appeals from the decision of the United States District Court for the Eastern District of Michigan granting summary judgment of invalidity of claims 1-44 of U.S. Patent 5,231,253 under 35 U.S.C. § 112, ¶ 1. ... Because we conclude that the asserted claims of the ’253
The technology at issue involves crash sensing devices for deployment in an occupant protection apparatus, such as an airbag, during an impact or crash involving the side of a vehicle. ATI is the assignee of the ’253 patent, entitled “Side Impact Sensors.” The invention is directed to a velocity-type sensor placed in a position within a vehicle in order to sense a side impact. A velocity-type sensor is a sensor that triggers when a velocity change sensed in a crash exceeds a threshold value. Representative claim 1 reads as follows:

A side impact crash sensor for a vehicle having front and rear wheels, said sensor comprising:

(a) a housing;
(b) a mass within said housing movable relative to said housing in response to accelerations of said housing;
(c) means responsive to the motion of said mass upon acceleration of said housing in excess of a predetermined threshold value, for initiating an occupant protection apparatus; and
(d) means for mounting said housing onto at least one of a side door of the vehicle and a side of the vehicle between the centers of the front and rear wheels, in such a position and a direction as to sense an impact into the side of said vehicle.

’253 patent, col. 10, ll. 59 – col. 11, ll. 1-5.

The prior art sensors used for sensing side impacts were crush sensor devices configured to trigger only when crushed or deformed, thereby closing a circuit. Such sensors, however, are deficient in that they will not trigger during a crash in which a side door is not hit directly but the impact is severe enough such that the occupant would need the protection of an airbag. Velocity-type sensors, on the other hand, can be adjusted to a desired sensitivity to detect a side impact and deploy an airbag, even though the side door is not directly hit. According to ATI, conventional wisdom was that velocity-type sensors, which had been successfully used for sensing impacts to the front of a vehicle, would activate too slowly to deploy an airbag during a side impact crash. The inventors of the ’253 patent discovered that velocity-type sensors when properly designed could successfully and timely operate to deploy an airbag in a side collision. An example of a velocity type sensor according to the invention is illustrated [in Figure 1 from the ’253 patent]:

When installed on a vehicle, the sensor faces the outside of the side door in the direction of the arrow B. When the sensor is subjected to a crash pulse of sufficient magnitude and duration, the flapper 11 moves toward the second contact 18. The first contact 17 engages with the second contact 18 and closes an electrical circuit to initiate deployment of an airbag. Because side impact sensors require greater insensi-
tivity for short, impulsive velocity changes, the specification discloses that an inertially damped sensor is the most suitable type of sensor for properly sensing side crashes. The specification states, however, that other sensors that are simpler and easier to manufacture, can be used to effectively sense a side impact. Such sensors include spring-mass sensors and viscously-damped sensors.

The specification also states that an electronic sensor assembly can be used to sense side impacts. ’253 patent, col. 10, ll. 1-15. The following figure, Figure 11, depicts such an electronic sensor assembly[.] The accompanying text states that Figure 11 is a “conceptional view of an electronic sensor assembly 201 built according to the teachings of this invention. This sensor contains a sensing mass 202 which moves relative to housing 203 in response to the acceleration of housing 203 which accompanies a side impact crash.” The specification further states that the motion of the sensing mass “can be sensed by a variety of technologies using, for example, optics, resistance change, capacitance change or magnetic reluctance change.” The enablement of this electronic side impact sensor is at issue in this appeal.

In May 2001, ATI filed a complaint against numerous defendants in the automotive industry, alleging infringement of the ’253 patent. In September 2003, the district court conducted a Markman hearing, and, in March 2004, the court issued an order construing the relevant claims. Relevant to this appeal, the court construed the phrase, “means responsive to the motion of said mass upon acceleration of said housing in excess of a predetermined threshold value, for initiating an occupant protection apparatus.” The parties agreed, and the court found, that the limitation was in means-plus-function format and that the stated function is initiating an occupant protection apparatus. The parties disagreed as to the structure corresponding to the claimed function. ATI contended that the corresponding structure included not only mechanical switch assemblies, but also electronic switch assemblies, as identified in the specification. The defendants countered that the only clearly linked structure identified in the specification is a mechanical switch assembly.

The district court agreed with ATI that the specification contains structure corresponding to the claimed function in the form of mechanical and electronic means. The court noted that the specification includes several descriptions of mechanical switches as preferred embodiments that would perform the intended function of initiating an occupant protection apparatus. The court also observed that Figure 11 and its accompanying textual description in column 10, lines 3-14, describe, albeit in vague detail, an alternative structure for initiating the occupant protection apparatus in the form of an electronic switch. The court concluded:

Corresponding structure includes mechanical switches with two contacts that engage in response to a force of sufficient magnitude and duration, and their equivalents. The specification identifies such mechanical switches in Figures 1 and 2 at column 6, lines 7-32; Figure 5 at column 8, lines 53-60; Figure 6 at column 8, lines 61-66; and Figures 8 and 9, lines 30-60. Corresponding structure also includes an electronic switch or assembly as described in Figure 11 at column 10, lines 3-14, of the patent specification
and its equivalents. The electronic switch or assembly contains a sensing mass that moves relative to the housing in response to the acceleration of the housing caused by a side impact crash.

... 

After the district court issued its claim construction order, various defendants including Honda Motor Co., DaimlerChrysler Co., Ford Motor Co., Hyundai Motor Co., Mazda Motor Co., and Saab Cars Sales USA, Inc., filed a motion for summary judgment that claims 1-44 are invalid for failing to comply with the written description requirement under 35 U.S.C. § 112, ¶ 1. Delphi Corporation also filed a motion for summary judgment that the claims that cover an electronic side impact sensor are invalid for lack of enablement. The court addressed and granted both motions ...

... 

The district court next granted Delphi’s motion for summary judgment of invalidity for lack of enablement. Delphi argued that the claims of the ’253 patent that cover an electronic sensor were invalid for failing to teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The court noted that the corresponding structure for the “means responsive” claim limitation included both mechanical means and electronic means and therefore the full scope of the claims included both types of sensors. The court determined, however, that the specification failed to enable electronic sensors for sensing side impacts. The court reasoned that the specification failed to provide sufficient details to teach a person of ordinary skill in the art how to make and use an electronic sensor. The court observed that not only did ATI’s representative admit that the specification failed to disclose structure for the general references to sensing technology, but that Figure 11, the only depiction of an electronic sensor in the ’253 patent, was not meant to represent any specific design of an electronic sensor. Moreover, the court determined that the text describing Figure 11 was “vague” and that the specification “fails to disclose reasonable basic enabling structure to show how one skilled in the art would use existing electronic sensing technologies to achieve the desired novel characteristics of an electronic acceleration sensor.”

The district court also considered the factors set forth in In re Wands, 858 F.2d 731 (Fed. Cir. 1988), and concluded that they weighed in favor of a finding that undue experimentation would have been necessary to make or use an electronic side impact sensor based upon the disclosure. Relying on testimony from Delphi’s expert and ATI’s expert, the court found that the factors of quantity of experimentation necessary, the amount of direction or guidance presented in the specification, and the absence of a working example favored a finding of lack of enablement.

The district court finally considered and rejected ATI’s argument that the claims are enabled because one embodiment or mode of practicing the invention, viz., a mechanical means, is enabled. The court noted that ATI “vigorously advocated” for and obtained a broad claim construction that both mechanical and electrical sensors be included within the scope of the claims. Because the specification does not enable both the mechanical and electronic side impact sensors, the court
concluded that the full scope of the claims was not enabled and that the claims are invalid for lack of enablement.

Discussion

We review a district court’s grant of summary judgment de novo, reapplying the standard applicable at the district court. Whether the subject matter of a patent claim satisfies the enablement requirement under 35 U.S.C. § 112, ¶ 1 is a question of law, reviewed de novo, based on underlying facts, reviewed for clear error. AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003). Because a patent is presumed to be valid, the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence. Id.

On appeal, ATI argues that because one embodiment of the invention is enabled, viz., a mechanical side impact sensor, the enablement requirement is satisfied. ... ATI further argues that, in any event, the specification does enable an electronic side impact sensor assembly. According to ATI, the specification discusses specific structure for an electronic side impact sensor and depicts such a structure in Figure 11. ATI contends that Delphi’s expert never addressed whether making an electronic side impact sensor based on the disclosure would require undue experimentation. ATI also contends that electronic sensors, albeit for sensing frontal impacts, were widely known at the time of filing and therefore there was no need for the specification to describe them in detail.

Delphi and General Motors (hereinafter collectively “Delphi”) respond that it is well established that the specification must enable the full scope of the claims as construed by the court, and the full scope of the claims includes mechanical side impact sensors and electronic side impact sensors. According to Delphi, providing an enabling disclosure of only mechanical side impact sensors is insufficient to satisfy the enablement requirement because the full scope of the claims is not enabled. Delphi further responds that the short recitation of an electronic sensor in the specification does not in fact enable an electronic side impact sensor because it does not teach one skilled in the art how to make and use such a sensor without undue experimentation. Delphi further responds that the specification expressly states that side impact sensing is a new field and hence ATI could not rely on the knowledge of one of ordinary skill in the art to supply the missing details. Moreover, Delphi asserts that the district court correctly found that the Wands factors, viz., the quantity of experimentation, the lack of direction or guidance presented, and the nature of the prior art, favor a conclusion of invalidity for lack of enablement.

We agree with Delphi that the district court correctly granted summary judgment that the asserted claims are invalid for lack of enablement. ... We have stated that the “enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.” AK Steel, 344 F.3d at 1244; see also Wands, 858 F.2d at 736-37.

The district court construed the relevant phrase “means responsive to the motion of said mass” to include both mechanical side impact sensors and electronic side impact sensors for performing the function of initiating an occupant protection apparatus. The parties do not dispute that construction; nor do they dispute that the specification enables mechanical side impact sensors. Under the district court’s con-
construction, however, that full scope must be enabled, and the district court was cor-
rect that the specification did not enable the full scope of the invention … .

… [A]lthough two full columns and five figures of the ’253 patent detail mechanical side impact sensors, only one short paragraph and one figure relate to an electronic sensor. Importantly, that paragraph and figure do little more than provide an overview of an electronic sensor without providing any details of how the electronic sensor operates. Figure 11 shows a very general view of an electronic side impact sensor. That figure only shows a boxed housing and a sensing mass. In contrast, Figure 1 shows a mechanical sensor in much more detail, making it clear from the figure how the sensor operates. The specification even states that Figure 11 is a “conceptional view” of an electronic sensor. This is supported by the statement of one of the inventors that Figure 11 “is not meant to represent any specific design or sensor or anything, just a concept.” Figure 11 represents a concept of an electronic sensor, not a figure providing details that would show one skilled in the art how to make or use an electronic side impact sensor.

Moreover, the textual description of Figure 11, which is the only description of an electronic sensor in the patent, provides little detail concerning how the electronic sensor is built or operated. The specification states the following:

FIG. 11 is a conceptional view of an electronic sensor assembly 201 built according to the teachings of this invention. This sensor contains a sensing mass 202 which moves relative to housing 203 in response to the acceleration of housing 203 which accompanies a side impact crash. The motion of the sensing mass 202 can be sensed by a variety of technologies using, for example, optics, resistance change, capacitance change or magnetic reluctance change. Output from the sensing circuitry can be further processed to achieve a variety of sensor response characteristics as desired by the sensor designer.

’253 patent, col. 10, ll. 3-14. That general description, however, fails to provide a structure or description of how a person having ordinary skill in the art would make or use an electronic side impact sensor. Indeed, inventor Breed admitted that the specification fails to disclose structure for any of the technologies mentioned. Noticeably absent is any discussion of the circuitry involved in the electronic side impact sensor that would provide more detail on how the sensor operates. The mere boxed figure of the electronic sensor and the few lines of description fail to apprise one of ordinary skill how to make and use the electronic sensor.

ATI argues that despite this limited disclosure, the knowledge of one skilled in the art was sufficient to supply the missing information. We do not agree. In Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997), we stated: “It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent. The novel aspect of this invention is using a velocity-type sensor for side impact sensing. During prosecution, ATI stated that prior to its invention, “it was assumed that [conventional] inertial sensors would actuate too slowly to deploy an air bag in a side impact situation” and also
that it “was unexpected that frontal impact sensors, properly designed, would work in sensing side impacts.” ATI further stated that the “essential concept of the invention” is to use “an inertial or acceleration sensor on a motor vehicle for sensing side impacts.” Thus, according to ATI, using inertial or acceleration sensors to sense side impacts represented a “breakthrough” in side impact crash sensing. Given that the novel aspect of the invention is side impact sensors, it is insufficient to merely state that known technologies can be used to create an electronic sensor. As we stated in Genentech, the rule that a specification need not disclose what is well known in the art is “merely a rule of supplementation, not a substitute for a basic enabling disclosure.” 108 F.3d at 1366. We further stated that the “omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.” Id.

Moreover, the specification states that: “Side impact sensing is a new field. The only prior art in the literature utilizes a crush sensing switch as a discriminating sensor to detect a side crash.” ’253 patent, col. 8, l. 45-47. In fact, ATI stated that at the time it filed the application for the ’253 patent, it did not know of any electronic sensors used to sense side impact crashes. Given that side impact sensing was a new field and that there were no electronic sensors in existence that would detect side impact crashes, it was especially important for the specification to discuss how an electronic sensor would operate to detect side impacts and to provide details of its construction. As was the case in Genentech, the specification provides “only a starting point, a direction for further research” on using electronic sensors for sensing side impact crashes; it does not provide guidance to a person of ordinary skill in the art on how to make or use an electronic side impact sensor. 108 F.3d at 1366. The specification fails to provide “reasonable detail” sufficient to enable use of electronic side impact sensors. Id.

The inadequacy of the description of an electronic side impact sensor is highlighted by comparison with the extensive disclosure of how to make and use a mechanical side impact sensor, consisting of two full columns. If such a disclosure is needed to enable making and using a mechanical side impact sensor, why is not a similar disclosure needed to enable making and using an electronic side impact sensor, which is an essential aspect of the invention?

In determining that undue experimentation would have been required to make and use an electronic side impact sensor, the district court properly relied on testimony from Delphi’s expert. Delphi’s expert discussed at length how a “great deal of experimentation” would have been necessary to make an electronic side impact sensor after reading the specification of the ’253 patent. He identified and discussed two distinct problems in developing an electronic side impact sensor: how to sense the motion of the mass in order to properly output a stream of data, and how to appropriately process the data. Moreover, Breed stated that based on his experience, electronic sensors for detecting side impact crashes could not be obtained commercially in 1990 and would have had to be developed. Inventor Breed admitted that he had never built an electronic sensor for side impact. The testimony from Delphi’s
expert and the inventor’s own testimony provide additional support for the conclusion of a lack of enablement.

ATI argues that its expert, Dr. Dix, testified that one skilled in the art would know how to adapt then-existing technology to create an electronic side impact sensor and that his testimony creates a genuine issue of material fact. Dix’s declaration states that electronic sensors were commercially available before the filing of the ’253 patent and that, based on engineering texts in 1989, one would have known how to select a commercial accelerometer, how to use analog circuits, and how to program and interface a microprocessor to process the signal using the existing prior art. Dix’s testimony, however, fails to discuss what types of tests would need to have been conducted to adapt existing electronic sensors for side impact sensing and does not provide any detail on how to adapt the existing technology. The testimony concludes that no undue experimentation was required to make an electronic side impact sensor, but, having failed to provide any detail regarding why no experimentation was necessary, the declaration does not create a genuine issue of material fact as to enablement.

We also reject ATI’s argument that because the specification enables one mode of practicing the invention, viz., mechanical side impact sensors, the enablement requirement is satisfied. We addressed and rejected a similar argument made in Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007). In that case, the invention was a front-loading fluid injector system with a replaceable syringe capable of withstanding high pressure for delivering a contrast agent to a patient. Id. at 1373. We construed the asserted claims, as urged by the patentee, to include an injector with and without a pressure jacket. Although the specification clearly enabled an injector with a pressure jacket, we concluded that it did not enable an injector without such a jacket and that the claims were invalid for lack of enablement. Id. at 1379. We stated that there “must be ‘reasonable enablement of the scope of the range’ which, in this case, includes both injector systems with and without a pressure jacket.” Id. at 1380.

Similarly, in this case, the claim construction of the relevant claim limitation resulted in the scope of the claims including both mechanical and electronic side impact sensors. Disclosure of only mechanical side impact sensors does not permit one skilled in the art to make and use the invention as broadly as it was claimed, which includes electronic side impact sensors. Electronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor compared with the well-enabled mechanical side impact sensor that is fully discussed in the specification. Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do.

We stated in Liebel: “The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet.” Id. at 1380. ATI sought to have the scope of the claims of the ’253 patent include both mechanical and electronic side impact sensors. It succeeded, but then
was unable to demonstrate that the claim was fully enabled. Claims must be enabled to correspond to their scope.

... **MagSil Corp. v. Hitachi Global Storage Techs.**

687 F.3d 1377 (Fed. Cir. 2012)

Rader, Chief Judge:

The [district court] granted summary judgment that claims 1-5, 23-26, and 28 of U.S. Patent No. 5,629,922 are invalid for a lack of enablement. Because the record supports the trial court’s judgment, this court affirms.

I.

Appellant Massachusetts Institute of Technology is the assignee of the '922 patent and appellant MagSil Corporation is the patent’s exclusive licensee. The application leading to the '922 patent was filed in March 1995 and issued in May 1997. The patent claims read-write sensors for computer hard disk drive storage systems. Hard disk drives store digital data in microscopic magnetic patterns on the surface of spinning platters, or disks, inside the drive.

As shown in Fig. 1, the '922 patent’s sensor uses a quantum mechanical effect where electric current can pass, or “tunnel,” from one electrode (e.g., 10) through a thin insulating barrier layer (14) into a second electrode (e.g., 12).

With two ferromagnetic electrodes, a tri-layer tunnel junction requires the current flow to depend on the magnetization direction of the electrodes. The junction resistance is higher when the magnetization direction of one electrode (e.g., 28 in 10) is antiparallel (i.e., having the opposite direction) to that of the other electrode (e.g., 28 in 12) and lower when the directions are parallel. Therefore, the tunnel junction resistance changes with a change in magnetization direction.

The '922 patent claims both a method of manufacturing a tri-layer tunnel junction and the junction itself. The asserted claims, however, only claim the tunnel junction device. Claim 1 is representative of the two asserted independent claims and reads:

1. A device forming a junction having a resistance comprising:
   a first electrode having a first magnetization direction,
a second electrode having a second magnetization direction, and
an electrical insulator between the first and second electrodes, wherein ap-
plying a small magnitude of electromagnetic energy to the junction revers-
es at least one of the magnetization directions and causes a change in the
resistance by at least 10% at room temperature.
(Emphasis added).

According to the background section of the '922 patent’s specification, scien-
tists had known “for many years” the basic theory underlying “tunnel resistance a-
rising from conduction electron spin polarization.” Past efforts, however, failed to
“produce an adequate level of change in the tunneling resistance (ΔR/R)” for prac-
tical applications. At room temperature, these past efforts had obtained only a 2.7%
change in resistance. The '922 invention, by contrast, achieved a “ten percent
change in the tunneling resistance with respect to magnetic field (H) variation,” in
some cases “as much as 11.8% change was seen.”

The specification further teaches that

[t]his increase in ΔR/R is believed to depend, inter alia, on a decrease in
surface roughness, which apparently directly couples the two electrodes fer-
romagnetically. Also, the quality of the intervening insulator between the
[electrodes] is significantly improved over the prior art devices. This is be-
lieved to be important in keeping the surface integrity of the [electrodes].

Col. 2, ll. 51-58. The asserted claims, however, do not include the process steps of
fabricating the device and require neither smoother layers nor a specifically improved
insulator. The specification also explains manufacture of the tri-layer tunnel junction
and ways to incorporate this device into read-write sensor heads for data storage.

MagSil filed suit in December 2008 against several defendants including Hitachi
Global Storage Technologies, Inc., Hitachi America, Ltd., Hitachi Data Systems
Corporation, and Shenzhen Excelstor Technology, Ltd. (collectively “Hitachi”),
alleging that their disk drive products infringe the '922 patent. The non-Hitachi de-
fendants have since been dismissed from the case. ... After Markman proceedings,
the parties filed cross-motions for summary judgment. The district court found the
asserted claims invalid as a matter of law for lack of enablement. The district court
entered its final judgment for Hitachi and MagSil timely appealed to this court ... .

II.

... Enablement is a question of law based on underlying factual findings. In re
Wands, 858 F.2d 731, 735 (Fed. Cir. 1988). A party must prove invalidity based on
non-enablement by clear and convincing evidence. Microsoft Corp. v. i4i Ltd., 131 S.
Ct. 2238, 2242 (2011); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1238-39 (Fed.
Cir. 2003). ... “To be enabling, the specification of a patent must teach those skilled
in the art how to make and use the full scope of the claimed invention without ‘un-
Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). The en-
ablement determination proceeds as of the effective filing date of the patent. Plant
Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention. See AK Steel, 344 F.3d at 1244. This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage. “The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) (quoting Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999)); see also In re Fisher, 427 F.2d 833, 839 (CCPA 1970) (“[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”).

The asserted claims of the ’922 patent broadly claim any tri-layer tunnel junction device wherein “applying a small magnitude of electromagnetic energy to the junction *** causes a change in the resistance by at least 10% at room temperature.” The district court construed the limitation “a change in resistance of at least 10%” as:

\[ \frac{\Delta R}{R} = \frac{(R_1 - R_2)}{R_1}, \]

where \( \Delta R/R \) represents the percent change in resistance, \( R_1 \) is the resistance of the junction before the application of electromagnetic energy reverses at least one of the magnetization directions, and \( R_2 \) is the resistance of the junction after the application of electromagnetic energy and the resultant reversal of at least one of the magnetization directions.

The district court further found that the asserted claims cover “resistance changes beyond 120% and up to infinity.” Thus, the specification at the time of filing must teach one of ordinary skill in the art to fully perform this method across that entire scope.

The record shows that MagSil advocated for a broad construction of this claim term. Its expert Dr. Murdock testified that this term covers tunnel junctions with resistive changes of 100% or more. Dr. Moodera, a named inventor, also testified that a 1000% change falls within the scope of the claims, despite that he had never made such a tunnel junction.

The specification—the disclosure available to show the full scope of enablement—teaches that the inventors’ best efforts achieved a maximum change in resistance of only 11.8% at room temperature. As the district court noted, MagSil has “not disclaimed the asserted claims’ infinite scope in the area of resistive change.” Accordingly, this record and specification show that the district court correctly discerned that the asserted claims are not enabled. The ’922 patent application was filed in March 1995. Hitachi has shown with clear and convincing evidence that one skilled in the art could not have taken the disclosure in the specification regarding “change in the resistance by at least 10% at room temperature” and achieved a change in resistance in the full scope of that term without undue experimentation.
The specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing. *Sitrick*, 516 F.3d at 1000. Here, the specification teaches that the fundamental science of the tunneling junction was known “for many years,” but past efforts did not produce effective use of the phenomenon. The specification discloses a 1975 publication by Michel Julliere that predicted an ideal tunnel junction could yield around a 24% change in resistance. Yet, the specification teaches that twenty years later, when the application was filed, the best achievement was an 11.8% change. Named inventor Dr. Meservey also testified that before the application was filed, he did not know how to achieve a tunnel junction with greater than 20% change in resistance.

During prosecution of the ’922 patent, MagSil stated that it had achieved resistive changes of 18% at this time after the date of filing. During prosecution MagSil also predicted still higher resistive changes because no clear theoretical limit prevented achieving the highest possible value of 100%. The inventors’ understanding during prosecution that a 100% resistive change was an upper limit is inconsistent with MagSil’s position at the time of this case. During this litigation, MagSil’s expert Dr. Murdock testified that a person of ordinary skill in the art could work from the ’922 patent and make tunneling junctions with a resistive change between 100% and 120% without undue experimentation.

Dr. Murdock’s aggressive view of the scope of this invention, however, runs counter to his own testimony that the first junction with this level of resistive change was not developed until 2006 or 2007. It also does not explain why it took some twelve years after the ’922 patent application was filed to achieve these results. Dr. Murdock also testified that experimentation on electrode metals and tunnel barrier insulator materials, as well as on the processes to make them, was needed to achieve these results. He further acknowledged that even someone of extraordinary skill in the art in 1995 could not have predicted the exact process and materials needed for the 120% resistive change achieved over ten years later.

Even if Dr. Murdock’s testimony could somehow overcome the requirement that the enabling disclosure must appear in the specification at the time of filing, his assertions also fail to reach the modern dimensions of this field of invention. His testimony (suggesting a resistive change between 100% and 120%) only reaches a lower-end of the claimed scope. The invention claims resistive changes from at least 10% up to infinity. Dr. Murdock admitted that resistive change of 604% has now been achieved by others, and the claim scope extends well beyond that value as well. The ’922 patent specification does not disclose working examples of tunnel junctions with resistive changes of 20%, 120%, 604%, or 1000%. The named inventors were not able to achieve even a 20% change a year after filing the application in 1995, and 604% junctions were not achieved until 2008.

In sum, this field of art has advanced vastly after the filing of the claimed invention. The specification containing these broad claims, however, does not contain sufficient disclosure to present even a remote possibility that an ordinarily skilled artisan could have achieved the modern dimensions of this art. Thus, the specification enabled a marginal advance over the prior art, but did not enable at the time of
filing a tunnel junction of resistive changes reaching even up to 20%, let alone the more recent achievements above 600%.

The trial court’s finding of an enablement deficiency falls squarely within this court’s precedent. See Fisher, 427 F.2d 833. In Fisher, the patent application was directed to a system for production of substances containing adrenocorticotropic hormone (ACTH) that were suitable for injection into humans for adrenal gland stimulation. 427 F.2d at 834. The claims recited a potency of “at least 1 International Unit of ACTH per milligram,” and the specification disclosed that previous experiments yielded compounds with a maximum potency of 50% or 0.5 International Units (“IU’s”). Id. The patent application, however, only disclosed compounds with ACTH potencies of between 111% and 230%, or 1.11 and 2.3 IUs per milligram. Id. The issue presented was whether an inventor who is the first to achieve a potency of greater than 1.0 for certain types of compositions, which potency was long desired because of its beneficial effect on humans, should be allowed to dominate all such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill. Id. at 839. The claims were not patentable because the specification did not enable ACTH potencies much greater than 2.3 IUs, when “at least 1” was claimed. Id. at 839.

Here, the claim term “change in the resistance by at least 10%” is very similar to the “open-ended” term in Fisher because it has a lower threshold, but not an upper limit. The asserted claims of the ’922 patent cover resistive changes from 10% up to infinity, while the ’922 patent specification only discloses enough information to achieve an 11.8% resistive change. The specification discloses that artisans hoped to achieve values of around 24%, but had not done so. During prosecution MagSil believed that the highest possible resistive change was 100%. Yet, the claims covered changes far above 20% or 100% even when the inventors could not explain any way to achieve these levels. As MagSil’s expert Dr. Murdock testified, since 1995 when the specification was filed, resistive changes now stretch up to above 600%.

The open claim language chosen by the inventors does not grant them any forgiveness on the scope of required enablement. Open claim language, such as the word “comprising” as a transition from the preamble to the body of a claim, “signals that the entire claim is presumptively open-ended.” Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1371 (Fed. Cir. 2005). “The transition ‘comprising’ creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrejected elements.” Crystal Semiconductor Corp. v. TriTech Microelectronics Int’l, Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001). MagSil seeks some easing of the enablement requirement by using this language in the asserted claims. To support its argument, MagSil refers to this court’s decision in Gillette.

In Gillette, the patentee claimed “[a] safety razor blade unit comprising *** a group of first, second, and third blades.” 405 F.3d at 1369. In that preliminary injunction case, this court noted that the claim used the ‘open’ claim terms ‘compris-
ing’ and ‘group of,’ in addition to other language, to encompass subject matter beyond a razor with only three blades.” Id. at 1371. This court looked to the claim language, specification, and prosecution history to find that the claim covered a razor with four blades. Id. at 1371-72. This court also noted that the open language of the claim “embraces technology that may add features to devices otherwise within the claim definition.” Id. at 1371.

MagSil contends that its open-ended threshold recitation of “at least 10%,” which when construed does not have an upper limit, is equivalent to Gillette’s open-language “comprising” recitation. Therefore, MagSil argues, if the “at least 10%” recitation is construed to not have an upper limit, then the “comprising” recitation as found in Gillette should also be construed to include every conceivable number of blades, up to infinity, which would not have been enabled. In the first place, enablement was not an issue in Gillette. Moreover, the safety razor technology and the very fact-specific distinctions in that case do not apply in this technology or case. In Gillette, for example, the open claim language entailed more than the “comprising” term and the construction was aided by the specification and prosecution history. In fact, the issue concerned whether the claim language covered an embodiment with more than one blade labeled as a “second blade,” where the terms “first, second, and third” did not specify the number of blades but specific characteristics of blades in those categories. Id. at 1372-73. Thus, the Gillette invention did not claim an infinite number of blades but blades with three separate categories of characteristics. Therefore, this case’s claim limitation extending to an open-ended range of values, which must be present for infringement, is different from a preamble recitation “comprising,” which does not exclude additional features to devices otherwise within the narrower claim definition. See id.

The ’922 patent specification only enables an ordinarily skilled artisan to achieve a small subset of the claimed range. The record contains no showing that the knowledge of that artisan would permit, at the time of filing, achievement of the modern values above 600% without undue experimentation, indeed without the nearly twelve years of experimentation necessary to actually reach those values. The enablement doctrine’s prevention of over broad claims ensures that the patent system preserves necessary incentives for follow-on or improvement inventions. In this case, for instance, many additional inventions and advances were necessary to take this technology from a 20% resistance change to the over 600% change in present data storage systems. Moreover this technology area will continue to profit from inventive contributions. Enablement operates to ensure fulsome protection and thus “enable” these upcoming advances.

MagSil’s difficulty in enabling the asserted claims is a problem of its own making. See Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) (“The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet.”) This court holds that the asserted claims are invalid for lack of enablement because their broad scope is not reasonably supported by the scope of enablement in the specification. See Fisher, 427 F.2d at 839. MagSil did not fully enable its broad claim scope. Therefore, it cannot
claim an exclusive right to exclude later tri-layer tunnel junctions that greatly exceed a 10% resistive change. *Id.*

III.

The district court entered summary judgment of noninfringement of the asserted claims after finding them invalid for lack of enablement. Hitachi’s disk drive products do not infringe the asserted claims because “[t]here can be no infringement of claims deemed to be invalid.” *Marrin v. Griffin*, 599 F.3d 1290, 1295 (Fed. Cir. 2010).

... 

**Written Description**

*Kennecott Corp. v. Kyocera Int’l, Inc.*

835 F.2d 1419 (Fed. Cir. 1987)

*Newman, Judge:*

Kennecott Corporation appeals [a] final judgment ... in which the district court granted summary judgment to the defendants Kyocera International and Kyoto Ceramic Co., Ltd. (together “Kyocera”), holding that United States Patent No. 4,179,299 is invalid in terms of the “on sale” bar of 35 U.S.C. § 102(b). Kennecott’s claim of patent infringement was dismissed. We reverse.

The Controlling Question

The judgment of invalidity turned on the sole question of whether the claims of the ’299 patent are entitled, as a matter of law, to the benefit of the filing date of its parent patent application which eventually issued as U.S. Patent No. 4,312,954, filed on June 5, 1975. If so entitled, the sales events in 1977 cannot effect an invalidity bar. If not so entitled, Kennecott admits that its sales activities occurred more than one year before May 1, 1978, the filing date of the continuation-in-part application that issued as the ’299 patent.

Background

On summary judgment all facts material to the result must be either undisputed or, if disputed, must be resolved in favor of the party opposing summary judgment. The question of the sufficiency of the disclosure of the ’954 application to support the ’299 claims is a matter of law based on underlying facts. All facts material to the issue are here deemed undisputed, based on admissions by Kyocera for the purpose of its motion for summary judgment.

Kyocera states in its brief on appeal that it did not concede or admit all the facts that Kennecott says it did. The district court found, however, that:

Finding 11. For the purposes of this Motion only, the material facts set forth in all of the affidavits and in all of the exhibits submitted by plaintiff in opposition to Defendants’ Motion, are undisputed by defendants.

Kyocera has not assigned error to this finding, and it is bound thereby.
The continuation-in-part ’299 application contains a substantial part of the disclosure of the ’954 parent application, plus a description of and photomicrographs showing the equiaxed microstructure.\[^2\] [The photomicrographs from the ’299 patent are provided at the end of this opinion.] It is not disputed that the photomicrographs were of the product made and described in the ’954 application, and produced in the original examples.

The ’299 patent claims contain the words “equiaxed microstructure” that were not present in the ’954 specification and claims. This is the only difference at issue. ’299 patent claim 1 is representative:

1. A sintered ceramic body consisting essentially of:
   (a) from about 91 to about 99.85% by weight silicon carbide, wherein at least 95% by weight of the silicon carbide is of the alpha phase;
   (b) up to about 5.0% by weight carbonized organic material;
   (c) from about 0.15 to about 3.0% by weight boron; and
   (d) up to about 1.0% by weight additional carbon;
   and having a predominantly equiaxed microstructure.

Pertinent undisputed or conceded facts include the following:

- the high (over 95%) alpha silicon carbide ceramic body that is described in the ’954 application has an equiaxed microstructure;
- the ’954 application does not mention the equiaxed microstructure of the high-alpha silicon carbide ceramic body, nor state the requirements for forming such microstructure;
- the inventors knew that the high-alpha silicon carbide ceramic body had an equiaxed microstructure, and it was known that ceramics from high-alpha silicon carbide could have this structure;
- examples 1-30 in the ’954 application, all the examples using high-alpha silicon carbide, all produce a ceramic body having an equiaxed microstructure;
- the method set forth in the ’954 application using the high-alpha silicon carbide invariably produces a ceramic product having an equiaxed microstructure.

Kennecott asserts that the equiaxed microstructure is inherent in the structure produced in the ’954 application, and that the ’299 claims, which specifically name the equiaxed structure, therefore enjoy the benefit of the earlier filing date. Kennecott also asserts, and Kyocera denies, that Kyocera conceded the question of inherency in the course of conceding all disputed facts on its motion for summary judgment.

\[^2\] “Equiaxed microstructure” is the crystal structure of the silicon carbide in submicron size grains that are not highly elongated and that do not have exaggerated grain growth. As defined in the ’299 patent the ratio of the maximum dimension of the grains to the minimum dimension is less than 3:1.
It is apparent that Kyocera conceded the factual premises\(^3\) of inherency by conceding that examples 1-30 produced, without undue experimentation, a product having an equiaxed microstructure. What is disputed is the legal implication of this inherent production of an equiaxed product.

The district court concluded that for the '954 specification to meet the written description requirement, one reading the specification must know from the “four corners” of the document, without recourse to information outside the specification, that the ceramic product has an equiaxed microstructure. The district court held that the specification of the '954 application met the enablement requirement of § 112 but not the written description requirement, and thus that it was immaterial that the product disclosed in the '954 application was the same as that claimed in the '299 patent.

Discussion

For the '299 claims to receive the benefit of the '954 application’s filing date, 35 U.S.C. § 120 requires, \textit{inter alia}, that the invention of the claims be disclosed in the '954 specification in the manner required by 35 U.S.C. § 112, ¶ 1[.]

The purpose of § 112, ¶ 1, is to ensure that there is an adequate disclosure of the invention for which patent rights are sought. The purpose of the description requirement of this paragraph is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.

The incorporation of the requirements of § 112 into § 120 ensures that the inventor had possession of the later-claimed invention on the filing date of the earlier application. \textit{In re Edwards}, 568 F.2d 1349, 1351 (CCPA 1978). The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention. A description that does not meet this requirement is legally insufficient. \textit{In re Wilder}, 736 F.2d 1516, 1520 (Fed. Cir. 1984).

It was undisputed that the only written description in the '299 application that was not present in the original '954 disclosure was the description and pictures of the product’s microstructure. Kennecott points to authority that the added description of a property of a previously disclosed product does not deprive claims to that product of the benefit of a prior disclosure of the product. Kyocera responds that because the '954 specification is silent as to the microstructure of the product, and because one would not know whether the product had an equiaxed microstructure merely by reading the specification, the specification is inadequate in law to support claims that require an equiaxed microstructure. Kyocera also asserts that the equiaxed microstructure is not obtained without physical manipulation of the process of the '954 application, and that any concession it may have made as to production of an equiaxed product is limited to the specific conditions used in examples 1-30 of the '954 specification.

\(^3\) Kyocera raises on this appeal factual issues that appear to contradict its concessions before the district court, including issues related to Kennecott’s representations to the patent examiner in prosecuting the '299 application. However, it is too late in the proceeding for Kyocera to retreat from its blanket concession of the factual issues.
Taking the last contention first, it was admitted that the products of examples 1-30 have the equiaxed microstructure, and that one skilled in this art could readily determine the microstructure of the product. Kyocera’s arguments on appeal as to the need for manipulation of conditions are contravened in the affidavit evidence referred to in Finding of Fact 11. We conclude that it was established before the district court that the high-alpha products of the ’954 application have the equiaxed microstructure.

On the issue of sufficiency of the earlier disclosure, the body of precedent teaches that the legal conclusion depends on the particular facts. In In re Edwards the court considered a chemical compound that was not described in the earlier application, and stated that the earlier and later applications need not use the identical words, if the earlier application shows the subject matter that is claimed in the later application, with adequate direction as to how to obtain it. The court observed that the chemical reactions described in the earlier filing “will inherently produce, as the predominant component, the [later claimed] compound.” 568 F.2d at 1352. The facts in Edwards are strongly analogous to those herein, for Kennecott’s ’954 examples 1-30 all produce a ceramic that has an equiaxed structure.

The facts before us ... are analogous to those discussed in In re Reynolds, 443 F.2d 384 (CCPA 1971). In Reynolds the question was whether words describing a function that was inherent in the claimed product could be added to the specification by amendment, or whether such description was “new matter” [prohibited by 35 U.S.C. § 132(a)†]. The court cited with approval the holding in Technicon Instruments Corp. v. Coleman Instruments, Inc., 255 F. Supp. 630, 640-41 (N.D. Ill. 1966), aff’d, 385 F.2d 391, (7th Cir. 1967), that

[b]y disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory, or advantage even though he says nothing concerning it.

Quoted [in Reynolds,] 443 F.2d at 389. It was concluded that the express description of the inherent property, since not “new matter,” could be added to the specification with effect as of the original filing date.

The Court of Customs and Patent Appeals has long recognized that an invention may be described in different ways and still be the same invention. In In re Kirchner, 305 F.2d 897, 904 (CCPA 1962), the court held that compliance with § 120 “does not require that the invention be described in the same way, or comply with § 112 in the same way, in both applications.” Id. In Kirchner the court authorized the addition to the specification of descriptive matter concerning the use of the compounds without loss of the parent application’s filing date. In the ’299 patent, by contrast, the additional material was added not only to the specification, but to the claims. Thus Kyocera argues that it is immaterial that the product in the ’299 claims is inherently the same as that produced in the ’954 application, because unlike Kirchner the ’299 claims include the new descriptive matter.

† [ Ed. Note: According to the last sentence of § 132(a), “No amendment shall introduce new matter into the disclosure of the invention.” ]
The Court of Customs and Patent Appeals did not adopt the position that is now urged by Kyocera. In *In re Nathan*, 328 F.2d 1005, 1008-09 (CCPA 1964), the court held that the later-added limitation to the claims of the compound's alpha orientation was "an inherent characteristic" of the claimed subject matter, and reversed a new matter rejection. ...

In this case, the invention of the '299 claims is a ceramic product. That product is the same as the product in the '954 application, and has the same structure. It was conceded that anyone with a microscope would see the microstructure of the product of the '954 application. The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result.

We conclude that the district court erred in holding that the '299 claims were not entitled to the '954 filing date.
298 F.3d 1290 (Fed. Cir. 2002)

Michel, Judge:

Plaintiff-Appellant New Railhead Manufacturing ("New Railhead") owns United States Patent No[]. 5,899,283 ... drawn to a drill bit for horizontal directional drilling of rock formations ... . New Railhead sued Vermeer Manufacturing Company ("Vermeer") and Earth Tool Company ("Earth Tool"), for infringement ... based upon their manufacture and distribution, respectively, of a competing drill bit. Both patents-in-suit were invalidated under 35 U.S.C. § 102(b). ... New Railhead appeals. We affirm.

I

Horizontal (or lateral) directional drilling is necessary, for example, when installing utilities around immovable objects such as roadways, rivers, or lakes. David Cox, co-owner of New Railhead, invented the drill bit ... claimed in the ’283 [patent] to overcome prior art problems with horizontal drilling through hard rock formations. The boring system disclosed by the Cox patent[] uses a drill bit with a body that contains fixed and semi-floating cutting points and one or more fluid channels to lubricate and disperse formations that have been cut or fractured, without using jetting fluids that are traditionally used to steer such drilling apparatus. Claim 1 of the ’283 patent is representative of the seven product claims (emphasis on pertinent claim limitation):

An asymmetric drill bit for horizontal directional drilling in rock, comprising:

a bit body attached to an end of a sonde housing;

the unitary bit body being angled with respect to the sonde housing the bit body being nonmovable with respect to the sonde housing in drilling operation; and

the bit body being mounted with a plurality of substantially forward-facing end studs extending from a front face of the bit body.

...

The ’283 patent was] filed as [a] continuation-in-part application[] that claimed the priority date of a provisional application filed by New Railhead on February 5, 1997. That provisional discloses a “directional earth boring tool” wherein “the heel-down method of attachment [of the bit] to the drill body helps to create the random elliptical orbital motion that causes the high impact fracturing technique.” Under headings labeled “Operational assumptions” and “Theory of Operation,” the provisional application further alludes to the “high included angle offsets for directional steering,” and the enhanced performance that results from “multiplying the fracturing effect through leverage on the main drilling points.” The provisional concludes with two drawings that show the bit and the sonde housing that holds the bit during operation; however, both drawings show the drill bit in an “exploded” view, i.e., the bit is not shown attached to the drill bit housing. Moreover, nowhere in the provisional application is the bit body expressly described as being
“angled with respect to the sonde housing” as recited in claim 1 of the ’283 patent. (As noted by the district court, Cox testified that the claim language “angled with respect to the sonde housing” meant that the drill bit had a toe (front portion) and a heel (rear portion), and that the toe-to-heel ratio was “the amount above and the amount below [the] outer circumference of the sonde housing.”)

The ’283 patent issued on May 4, 1999, and New Railhead filed this lawsuit the following day. …

At the close of discovery, Earth Tool moved for partial summary judgment of invalidity of the ’283 patent based on the on-sale bar of 35 U.S.C. § 102(b). The parties did not dispute that commercial embodiments of the patented drill bit were sold during the spring and summer of 1996—more than one year before the November 1997 filing date of the non-provisional application, but not more than one year before the filing date of the February 1997 provisional application to which it claimed priority. Earth Tool argued, however, that the utility application was not entitled to the priority date of the provisional because the disclosure in the provisional specification failed to adequately describe the invention claimed in the ’283 patent as required by 35 U.S.C. § 119(e)(1). The district court agreed, concluding “nothing in this [provisional specification] language states that the drill bit is ‘angled with respect to the sonde housing’ or otherwise describes the toe, the heel, or the toe-to-heel ratio.” The court further found that Cox had admitted as much in his deposition, and that his later contrary declaration submitted in opposition to partial summary judgment could not, as a matter of law, create a genuine issue of material fact on this point. Thus, because the ’283 patent was not entitled to claim the priority date of the provisional, New Railhead’s mid-1996 commercial sales constituted a § 102(b) bar.

... 

III

Because the parties do not dispute that the patented drill bit was the subject of a commercial offer for sale more than one year before the utility application was filed, the ’283 patent is invalid if it is not afforded the priority date of the provisional application. 35 U.S.C. § 102(b).

As a part of the Uruguay Round Agreements Act, the Patent Statute was amended to allow applicants for United States patents to file provisional applications that could provide the priority date for a non-provisional utility application filed within one year of the provisional. See 35 U.S.C. § 111(b). Such a provisional application need only include a specification conforming to the requirements of 35 U.S.C. § 112, ¶ 1, and at least one drawing filed under § 113; no claims are required. 35 U.S.C. §§ 111(b)(1), (2). However, for the non-provisional utility application to be afforded the priority date of the provisional application, the two applications must share at least one common inventor and the written description of the provisional must adequately support the claims of the non-provisional application:

An application for patent filed under section 111(a) … of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this
title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) ... of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

35 U.S.C. § 119(e)(1) (emphasis added). In other words, the specification of the provisional must “contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,” 35 U.S.C. § 112, ¶ 1, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.

New Railhead argues that the district court erred by concluding that the specification of the provisional did not support the claims of the ‘283 patent. In particular, New Railhead asserts that Cox was always in possession of the asymmetrical heel-toe structure and that the district court went astray by focusing on whether the provisional application disclosed the “importance” of the angled structure rather than whether it disclosed the angled structure at all. In its view, one of ordinary skill would readily understand from the “totality of the disclosure,” i.e., the drawings together with the provisional written description, that the drill bit was angled with respect to the sonde housing.

We discern no error in the district court’s conclusion that this claim limitation was not adequately supported by the provisional, as the factual bases girding its conclusion are so solid that no reasonable jury could find otherwise. The district court relied in particular on the admissions in the deposition testimony of Cox himself, in which he explained that he knew the drawings contained the heel-toe angle because he understood the configuration of the device, not necessarily because the drawings showed such a configuration. In addition to Cox’s testimony, the district court had before it the testimony of Joseph Steele, the New Railhead employee responsible for the company’s research and development (and the person aside from Cox most familiar with the patented drill bit), who averred that he could not tell from the drawings in the provisional whether the heel and toe of the drill bit extended beyond the sonde housing. Randy Runquist, a designer and engineer for Vermeer testified that he, too, was unaware of the angled features of the drill bit from the provisional drawings.

Cox’s later declaration, submitted in opposition to the motion for partial summary judgment, was at best an equivocal attempt to refine his deposition testimony. But even when viewed in a light most favorable to New Railhead, one is left with no clear indication that the provisional application adequately describes to one of ordinary skill in the art the “heel-toe” angle between the bit and the housing:

To my eye the drawings which were submitted with the provisional application clearly show a heel portion and a toe portion, each of the portions extending respectively above and below the outer circumference of the sonde housing. Although the drawings show the two pieces in exploded configuration, I believe that because they are accurately scaled drawings of
the actual tool, one of ordinary skill could actually construct the tool itself from these drawings and if that were done, the heel and toe portions would be present.

(Emphases added). This averment not only fails to create a genuine issue of material fact regarding whether the written description has been satisfied, but it also conflates the concepts of written description and enablement in the process. “The purpose of the written description requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). That is, the disclosure must show he had invented each feature that is included as a claim limitation. The adequacy of the written description (i.e., the disclosure) is measured from the face of the application; the requirement is not satisfied if one of ordinary skill in the art must first make the patented invention before he can ascertain the claimed features of that invention. Cf. Martin v. Mayer, 823 F.2d 500, 505 (Fed. Cir. 1987) (“It is not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure [but] whether the application necessarily discloses that particular device.”) (quoting Jepson v. Coleman, 314 F.2d 533, 536 (CCPA 1963)).

New Railhead’s repeated assertions that Cox was at all times in possession of the claimed invention are somewhat misdirected. Although we have recently noted the particular usefulness of the “possession” inquiry when a patentee claims an earlier filing date under 35 U.S.C. § 119, we have at the same time cautioned that the written description requirement is not subsumed by the “possession” inquiry. Identity of description is not necessary. See, e.g., Crown Operations Int’l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002) ("[T]he disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue."). Identity of that which is described, however, is necessary: “What is claimed by the patent application must be the same as what is disclosed in the specification ***.” Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002); accord Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997). The description in the provisional fails to meet this standard.

Undeterred, New Railhead argues that the testimony credited by the district court demonstrates at most that the provisional drawings alone do not satisfy the written description requirement, but that—read in conjunction with the rest of the specification—the adequate support requirement of § 112, ¶ 1, has been met. In particular, it assails the district court for having allegedly focused only on the abstract of the specification, and urges that the following excerpt from the provisional, with particular emphasis placed by New Railhead, discloses to one of ordinary skill the angled structure:

Theory of operation—
* * *

3. The new Asymmetrical Directional Drilling point for Rock and Hard Earth Formations combines the techniques of point contact fracturing for rock with a high angle of attack for hard earth as well as soft formations.
Fracturing is accomplished with the application of hard carbide points on random elliptical torque vectors created as the asymmetrical geometry of the bit forms eccentric rotational paths by the combination of rotation and thrust moments. Drilling of rock like shales that are typically considered to be compressed and extremely dense and dry clays are also enhanced by the aggressively pointed geometry of the drill bit.

4. The asymmetrical geometry enhances the performance of the drill rack by multiplying the fracturing effect through leverage on the main drilling points. As the bit rotates the offset drill points randomly fracture and engage as center points of rotation and multiply transverse moments 3 to 8 times the actual transverse moments that can be produced at the same diameter in a symmetrically formed fixed diameter drill bit.

5. Bore hole size is defined and controlled by stabilizing the forward cutting points on a trailing shoe that contains replaceable, semi-permanent carbide buttons that will fracture off irregular surfaces and help smooth the borehole as well as reduce the abrasive wear on the body of the bit.

We are not moved. Nothing in this disclosure even intimates to one of ordinary skill in the art the specific angled relationship between the bit and its housing. Contra ’283 patent, col. 2, ll. 49-57 (“[T]he specially-configured asymmetric drill bit for horizontal directional drilling in rock includes a bit body attached to an end of a sonde housing. The bit body is angled with respect to the sonde housing, as best shown in Fig. 4, with the angle displacement from collinear alignment being relatively slight, that is, on the order of about 15 degrees.”). Notably, while the patent discloses verbatim the language from the provisional “theory of operation” quoted by New Railhead, see id. col. 3, l. 49 – col. 4, l. 5, the provisional never states that the drill bit is angled with respect to the sonde housing, does not mention or describe the toe or the heel, and does not mention or define the heel-toe ratio. The passing references to a “high angle of attack” and “high included angle offsets” in the provisional, divorced from any discussion whatsoever of the bit-housing combination, do not convey to one of ordinary skill that Cox was in possession of the bit-housing angle that is a limitation of the invention claimed in the ’283 patent.

New Railhead has failed to demonstrate any error in the district court’s holding that the disclosure of the provisional application does not adequately support the invention claimed in the ’283 patent as to the angle limitation. As a result, the ’283 patent is not entitled to the filing date of the provisional application. 35 U.S.C. § 119(e)(1). Accordingly, because the utility application that issued as the ’283 patent was filed on November 12, 1997, more than one year after the admitted mid-1996 commercial offers for sale, the district court properly granted Vermeer’s motion for partial summary judgment of invalidity under 35 U.S.C. § 102(b).
PowerOasis, Inc. v. T-Mobile USA, Inc.
522 F.3d 1299 (Fed. Cir. 2008)

Moore, Judge:

PowerOasis, Inc. and PowerOasis Networks, LLC (PowerOasis) appeal the ... grant of summary judgment that claims 15, 18, 31, 35, 38, 40, and 49 (asserted claims) of U.S. Patent Nos. 6,466,658 and 6,721,400 are invalid as anticipated under 35 U.S.C. § 102(b). In reaching its decision, the district court concluded that none of the asserted claims of the two patents were entitled, under 35 U.S.C. § 120, to the benefit of the filing date of PowerOasis’s original application because the earlier application did not provide a written description of the invention claimed in the asserted patents, as required by 35 U.S.C. § 112. We affirm the grant of summary judgment of invalidity with respect to all asserted claims.

Background

The two PowerOasis patents at issue, the ’658 patent and the ’400 patent (PowerOasis patents), are directed to vending machines that sell telecommunications access. The PowerOasis patents contain virtually identical specifications. The stated purpose of the PowerOasis patents is to provide a “vending machine” that enables a customer to connect a laptop to a telecommunications channel. The ’658 and ’400 patents list filing dates of November 6, 2001 and October 15, 2002, respectively. The ’658 and ’400 patents stem from a series of continuation and continuation-in-part applications. The first application in the patent chain (Original Application) was filed on February 6, 1997 and ultimately issued as U.S. Patent No. 5,812,643. PowerOasis does not assert the ’643 patent in this litigation.

PowerOasis filed a continuation application on September 18, 1998 (which was later abandoned), and on June 15, 2000, it filed a continuation-in-part application (2000 CIP Application), which issued as U.S. Patent No. 6,314,169. The ’169 patent is not asserted by PowerOasis in this litigation. The 2000 CIP Application added considerable new language to the specification, which the district court characterized as “substantial new matter.”

PowerOasis subsequently filed the two applications that led directly to the two patents asserted in this suit: first the ’658 patent, then the ’400 patent. PowerOasis sued T-Mobile for patent infringement alleging that T-Mobile’s wireless “HotSpot Network” infringes claims 15, 18, 31, 35, 38, 40, and 49 of both PowerOasis patents. Each of the asserted claims depends from independent claim 1, which is not asserted by PowerOasis. Except for minor variations in the language of the independent claims that do not relate to the issues on appeal, the language of the asserted claims is identical in both PowerOasis patents. Independent claim 1 recites:

1 The relevant features of the T-Mobile HotSpot Network are undisputed. Unlike a stand-alone vending machine that vends telecommunications access, the T-Mobile HotSpot Network consists of several main components that are geographically distributed throughout the United States. These components work together to enable users to access Internet services. Multiple users can simultaneously access the T-Mobile HotSpot Network.
1. A vending machine for vending telecommunications channel access to a customer, said vending machine comprising:

- a payment mechanism for obtaining information from the customer to initiate a vending transaction;

- a customer interface for indicating the status of said vending machine;

- an electronic circuit for determining when the vending transaction is completed;

- a telecommunications channel access circuit ... ;

- a telecommunications channel access connector ... ; and

- a control unit having a device for receiving payment information from the customer and for controlling said electronic circuit and said telecommunications channel access circuit.

The parties had agreed that “customer interface” is “an interface that enables information to be passed between a human user and hardware or software components of a system,” but disagreed about the location of the customer interface. PowerOasis argued that the “customer interface” may occur on a customer’s laptop. T-Mobile argued that the customer interface must be located on the vending machine itself. Relying entirely on new language added to the 2000 CIP application, the district court adopted PowerOasis’s proposed construction that the claim term “customer interface” encompasses an interface that is located on the customer’s laptop.

In light of the district court’s construction of “customer interface,” T-Mobile filed a motion for summary judgment that the asserted claims were anticipated by the MobileStar Network. It is undisputed that prior to June 15, 1999, MobileStar Networks, Inc. (a company acquired by T-Mobile in 2002) developed, deployed, publicly used, and offered for sale the MobileStar Network, which was a high-speed wireless data network that connected users to the Internet. It is also undisputed that prior to June 15, 1999, the MobileStar Network contained all of the same features that form the basis of PowerOasis’s allegation that the T-Mobile HotSpot Network infringes its patents. T-Mobile argued, therefore, that this public use, sale, and offer for sale more than one year prior to the June 15, 2000 filing date of the 2000 CIP Application constituted § 102(b) prior art which anticipated the PowerOasis patents. PowerOasis responded by claiming its asserted claims should have the benefit of priority going all the way back to the filing date of its Original Application (February 6, 1997) which would antedate the MobileStar Network.

On summary judgment, the district court determined that the asserted claims were not entitled to the priority date of the Original Application because the written description of the Original Application did not support the later issued claims. The district court noted that, to arrive at the broad construction it accorded the “customer interface,” it relied “exclusively” on the new matter that was added to the 2000 CIP Application. Because the district court concluded that the ’658 and ’400

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2 T-Mobile does not dispute that the ’658 and ’400 patents are at least entitled to the effective filing date of the 2000 CIP Application, June 15, 2000.
patents are not entitled to the effective filing date of the Original Application, the district court granted the motion for summary judgment of invalidity. This appeal followed.

Discussion

PowerOasis appeals two aspects of the district court’s summary judgment determination. First, PowerOasis argues that the district court erred when it placed the burden of proof on PowerOasis to show that it is entitled to the priority date of the Original Application. Second, PowerOasis argues that the district court erred in concluding that the disclosure of the Original Application does not provide a written description adequate to support the asserted claims of the ’658 and ’400 patents. See 35 U.S.C. § 112 ¶ 1. PowerOasis contends that, at a minimum, there is a genuine issue of material fact which prevents summary judgment of invalidity. We consider each issue in turn.

I. Burden of Proof

It is well established that a patent is presumed valid, and “the burden of persuasion to the contrary is and remains on the party asserting invalidity.” Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1573 (Fed. Cir. 1985). The district court acknowledged a challenged patent is entitled to a presumption of validity, but questioned whether the presumption of validity extends to the question of priority. The district court concluded that “when a dispute arises concerning whether a CIP patent is entitled to priority to the date of the original application and the Patent Office has not addressed the issue, the burden of proof ordinarily should rest with the party claiming priority to the date of the original application.” Accordingly, the district court held that PowerOasis had the burden of proving that it is entitled to claim priority to the filing date of the Original Application.

PowerOasis contends that the party asserting invalidity must always bear the burden of proof as to whether claims in a patent application are entitled to the priority date of a parent application. PowerOasis relies on this court’s decision in Ralston for support of its position that the party attacking validity bears the burden to show that claims stemming from a CIP application are not entitled to an earlier filing date. In short, PowerOasis argues the presumption of validity should include a presumption that claims in a CIP are all entitled to the earliest effective filing date.

3 A “CIP” application is a continuation-in-part application containing a portion or all of the disclosure of an earlier application together with added matter not present in that earlier application. Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 555 (Fed. Cir. 1994) (citing MPEP § 201.08). While the PTO has noted that the expressions “continuation,” “divisional,” and “continuation-in-part” are merely terms used for administrative convenience, the quintessential difference between a continuation and a continuation-in-part is the addition of new matter.
interference, which awarded the inventor the benefit of his earliest application in a
detailed opinion by the Board. The district court in Ralston properly accorded
deference to the Board’s decision on priority.

Additionally, the § 102(a) prior art on which the defendant in Ralston relied
was brought to the attention of the examiner during prosecution. “When an attack-
er simply goes over the same ground traveled by the PTO, part of the burden is to
show that the PTO was wrong in its decision to grant the patent.” Am. Hoist &
Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984) (emphasis in
original). This court has explained that:

When no prior art other than that which was considered by the PTO ex-
aminer is relied on by the attacker, he has the added burden of overcoming the
deferece that is due to a qualified government agency presumed to have
properly done its job, which includes one or more examiners who are
assumed to have some expertise in interpreting the references and to be
familiar from their work with the level of skill in the art and whose duty it
is to issue only valid patents.

Id. at 1359. In Ralston, accordingly, the defendant had the added burden of over-
coming the deference due to the PTO.

In contrast to Ralston, in this case, the PTO did not, at any point, make any de-
termination with regard to the priority date of the various claims of the asserted
patents. There was no interference in this case related to the asserted patents or the
2000 CIP Application that awarded PowerOasis the benefit of priority for its Origin-
al Application nor was there any determination of priority during prosecution inci-
dent to a rejection. The MobileStar Network prior art was never considered by the
examiner. In fact, in this case the PTO did not make a determination regarding the
priority date for the asserted claims with respect to any reference.

In the absence of an interference or rejection which would require the PTO to
make a determination of priority, the PTO does not make such findings as a matter
of course in prosecution.4 The PTO’s own procedures indicate that examiners do
not make priority determinations except where necessary:

Unless the filing date of the earlier nonprovisional application is actually
needed, for example, in the case of an interference or to overcome a refer-

4 Determining the effective filing date each claim in a CIP application is entitled to
can be quite complex. Since CIPs generally add new matter, the claims may be fully
supported by the parent application or they may rely on the new matter for support.
See Michael J. Meurer & Craig Allen Nard, Invention, Refinement and Patent Claim
n. 24 (2005) (noting “[u]nder the new matter doctrine, revisions to the written de-
scription that occur after an application is filed may jeopardize the priority date de-
erived from that application”). In fact, a CIP could contain different claims entitled
to receive different effective filing dates in the same patent. There would be no
reason for the PTO to undertake what could be a very time consuming written de-
scription analysis simply to pronounce the effective filing date of each claim, absent
some dispute over it during prosecution.
ence, there is no need for the Office to make a determination as to whether the requirement of 35 U.S.C. § 120, that the earlier nonprovisional application discloses the invention of the second application in the manner provided by the first paragraph of 35 U.S.C. § 112, is met and whether a substantial portion for all of the earlier nonprovisional application is repeated in the second application in a continuation-in-part.

M.P.E.P. (7th ed. July 1998) at § 201.08. When neither the PTO nor the Board has previously considered priority, there is simply no reason to presume that claims in a CIP application are entitled to the effective filing date of an earlier filed application. Since the PTO did not make a determination regarding priority, there is no finding for the district court to defer to.

Of course, the fact that the MobileStar Network prior art was never before the PTO does not change the presumption of validity or who has the burden of proof with respect to the prima facie case of invalidity. See Am. Hoist, 725 F.2d at 1360. T-Mobile, the party asserting invalidity, must still show by clear and convincing evidence that the asserted patent is invalid. Once it has established a prima facie case of invalidity and its burden is met, “the party relying on validity is then obligated to come forward with evidence to the contrary.” Ralston, 772 F.2d at 1573.

T-Mobile established its prima facie case of invalidity with respect to the asserted claims. It is undisputed that the MobileStar Network was in public use more than one year prior to the June 15, 2000 filing date of the CIP Application. PowerOasis conceded that the MobileStar Network would infringe the claims of the ’658 and ’400 patents if it were in operation today. “[T]hat which would literally infringe if later in time anticipates if earlier.” Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003) (internal citation omitted). Accordingly, PowerOasis has conceded that unless the asserted claims are accorded an earlier filing date than the 2000 CIP Application, the MobileStar Network is § 102(b) prior art. Once T-Mobile established by clear and convincing evidence that the MobileStar Network was § 102(b) prior art to the asserted claims of the ’658 and ’400 patents, the burden was on PowerOasis to come forward with evidence to the contrary. The district court therefore correctly placed the burden on PowerOasis to come forward with evidence to prove entitlement to claim priority to an earlier filing date.

II. Written Description Requirement

Application of the written description requirement is central to the resolution of this appeal. “It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.” In re Chu, 66 F.3d 292, 297 (Fed. Cir. 1995); see also Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1302-03 (Fed. Cir. 1999) (“Different claims of [a CIP] application may therefore receive different effective filing dates. *** Subject matter that arises for the first time in [a] CIP application does not receive the benefit of the filing date of the parent application.”).

To satisfy the written description requirement the disclosure of the prior application must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.” Vas-Cath Inc.
Miller’s Patent Cases

v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis in original). While a prior application need not contain precisely the same words as are found in the asserted claims, see Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed. Cir. 1995); Purdue Pharma LP v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000) (holding that the disclosure does not have to provide in haec verba support in order to satisfy the written description requirement), the prior application must indicate to a person skilled in the art that the inventor was “in possession” of the invention as later claimed. Ralston, 772 F.2d at 1575. “Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.” In re Huston, 308 F.3d 1267, 1277 (Fed. Cir. 2002) (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)). In Lockwood, we held:

While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

107 F.3d at 1572. We have explained that to satisfy the written description requirement, “the missing descriptive matter must necessarily be present in the [original] application’s specification such that one skilled in the art would recognize such a disclosure.” Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed. Cir. 1998); see also Martin v. Mayer, 823 F.2d 500, 505 (Fed. Cir. 1987) (holding that the written description requirement is “not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure. *** Rather, it is a question whether the application necessarily discloses that particular device.”) (emphasis in original). This requires that the written description actually or inherently disclose the claim element. See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1118-20 (Fed. Cir. 2001) (holding that to comply with the written description requirement the location of the spring must be actually or inherently disclosed; that the location may be obvious from the disclosure is not enough); Tronzo, 156 F.3d at 1159 (holding a claim invalid for failure to satisfy the written description requirement when the specification did not disclose all cup shapes literally or “inherently”). Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party. See Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1072-73 (Fed. Cir. 2005).

Entitlement to the filing date of the Original Application would allow PowerOasis to antedate MobileStar Network, thereby removing it as a reference against the claims. The only evidence PowerOasis came forward with to antedate the MobileStar Network was the Original Application and the declaration of its expert witness. The district court analyzed both the Original Application and the declara-
tion of PowerOasis’s expert witness, and held that the asserted claims of the ’658 and ’400 patents are only entitled to the filing date of the 2000 CIP Application because PowerOasis did not prove it was “in possession” of the claimed invention when it filed its Original Application.

In this case, the district court’s determination that the Original Application does not provide a written description of “customer interface” as set forth in the asserted claims is correct. The Original Application described a vending machine with a “display” or “user interface” as part of the vending machine, rather than a vending machine with a “customer interface” located on a customer’s electronic device. The 2000 CIP Application added language describing a vending machine with a user interface located remotely from the vending machine, such as on a user’s laptop, as shown by the relevant new specification language underlined in the passages below:

The microprocessor also communicates with the customer via a user interface to provide details on the progress of the transaction. The user interface is not particularly limited and need not even include a visual display on the vending machine. ’169 patent, col. 2, l. 66 – col. 3, l.3.

Once attached and initiated, the customer can monitor the state of the vending machine and the transaction via the user interface. The user interface may be a visual display or some other type of progress indicator such as an auditory signal. For example, the vending machine could instruct or inform the user via an audio speaker. Alternatively, the user interface can be present inside or uploaded to the user’s laptop or other device thereby obviating the need for an interface within the vending machine unit. Similarly, the use of a card access system which prevents usage by ejecting the user’s card would also obviate the need for a visual or aural interface. Id. at col. 6, ll. 7-19.

Another object of this invention is portability. Using an internal power source and wireless telecommunications channels, this invention is not limited to a fixed location. In this configuration, the invention could be used at fairs, outdoor concerts and similar sites where permanent installations are not cost effective. In these cases, it might be more cost effective to have one control unit operating multiple vending machines. These multiple vending machines may be arranged in the form of a kiosk to allow multiple customers access to the vending machine at the same time. Similarly, almost any combination of functional components of the vending machine could be moved to a location remote from the machine. This could be accomplished, for example, by networking a cluster of machines to a server either on site or at a remote location. Id. at col. 4, ll. 17-31.

The 2000 CIP Application also substituted the term “customer interface” for the claim term “display” in claim 1 and added several independent claims disclosing a “vending machine” with component parts “located remote from said vending machine.”

The district court stated that it “cannot find a single reference in the written description which suggests that PowerOasis understood its invention to include the new matter that it claimed for the first time in the CIP Application.” We agree.
of the references from the Original Application that PowerOasis identifies as allegedly providing written description support for the later-issued claims are to a “user interface” that is part of a unitary vending machine.

All of the Original Application’s embodiments that include the user interface describe a physical display that is a part of the vending machine. As shown in Figure 2, “[t]he customer sees an operating panel 101 with a user interface 110 comprising two lights referred to as READY and AVAILABLE.” ’643 patent, col. 6, ll. 27-29.

“[I]n the preferred embodiment of Fig. 2, the user interface [110] consists of two lights which turn on and off in particular patterns to inform the customer as to how the transaction is processing.” Id. at col. 6, ll. 59-63. The only depiction of the user interface 110 is depicted as part of the vending machine. “When the customer first approaches the vending machine 100, the READY light is on.” Id. at col. 6, ll. 35-36 (emphasis added).

PowerOasis argues that the user interface “could take any number of possible forms.” To be sure, the specification describes other embodiments for the user interface. For example, “these lights may be replaced or augmented by a video display unit (VDU) which provides more detailed instruction to the customer on vending machine operation and detailed information on the progress of the transaction including accumulated charges.” The VDU “could be combined with a keyboard or other push-buttons that would allow the customer to set the language for the display, the connectors to be activated and, optionally, when to terminate the transaction.” In other embodiments, “the user interface includes a printer or similar device to provide the customer with a receipt for the transaction.” While the Original Application discloses multiple embodiments of the “user interface,” all such embodiments make the user interface part of the unitary vending machine apparatus. There is simply no disclosure in the Original Application of a user interface that is either located on a customer’s laptop or even separate from the vending machine itself.

Indeed, although Figure 5 of the Original Application depicts a laptop hooked up to the vending machine, the figure shows that the user interface is clearly located on the vending machine and not the laptop. In Figure 5 of the Original Application [shown below], a laptop computer is connected to the operating panel of the vending machine (501), which is mounted on the wall. The “user interface” is represented by the video display unit (510), which is located on the operating panel of the vending machine (502) and not on the laptop. Therefore, we agree with the district court that the Original Application did not contain support for a “customer interface” located on the customer’s laptop, which was the claim construction urged by PowerOasis and adopted by the district court.
This broad construction is supported only by the material added in the 2000 CIP Application. In fact, PowerOasis cited only to language first introduced in the 2000 CIP Application to support this broad construction … . Because none of this support was present in the Original Application and because the Original Application did not disclose a customer interface apart from the vending machine, the asserted claims are only entitled to the 2000 CIP Application filing date of June 15, 2000. Since it is undisputed that the MobileStar Network was in public use more than one year prior to this date, the asserted claims are invalid.

Further, we agree with the district court that PowerOasis’s conclusory expert declaration was not sufficient to raise a genuine issue of material fact regarding whether the Original Application disclosed to one skilled in the art a customer interface located on a customer laptop. The district court determined, and we agree, that Mr. Morley does not cite in a persuasive way any supporting references in the Original Application. He does not demonstrate how, at the time of the filing date of the Original Application, PowerOasis was in possession of the claimed invention, which uses a customer’s electronic device (e.g., a laptop) to achieve the customer interface. He does not show anywhere in the Original Application where a customer interface is located on a customer’s laptop either expressly or inherently. His declaration points to figures and discussions of the user interface in the Original Application, each of which is to a user interface on the vending machine. He goes on to say it is “well known to those of ordinary skill as of February 6, 1997, that the functionality of providing information to a customer via a user interface can be provided by displaying information on a computer screen, such as on a portable computer of the type referred to in the ’643 patent when that computer is connected to a network of other components and computers.” This is not a claim that use of a customer laptop as the customer interface is necessarily disclosed by the Original Application. At best, this is a statement that it would be obvious to substitute a customer laptop for the user interface disclosed on the vending machine. Obviousness simply is not enough; the subject matter must be disclosed to establish possession. See TurboCare, 264 F.3d at 1119; Tronzo, 156 F.3d at 1159; Lockwood, 107 F.3d at 1571-72. Therefore, the declaration by PowerOasis’s expert does not raise a genuine issue of material fact over whether the Original Application established that the inventor possessed the invention as later claimed, which includes a customer interface located on a customer laptop apart from the vending machine.

Finally, despite the fact that the district court adopted the very construction urged by PowerOasis for “customer interface” on appeal, PowerOasis argues that a
different construction ought to be used for validity purposes. PowerOasis’s argument boils down to a claim that PowerOasis is entitled to a broad claim construction for purposes of infringement and a different narrower claim construction for purposes of validity. See Oral Argument at 6:56-8:01, available at http://www.cafc.uscourts.gov/oralarguments/mp3/2007-1265.mp3; Appellant Brief at 18-24. PowerOasis contends that as long as the claim term “customer interface” was supported by the Original Application then the claims are entitled to the effective filing date of the Original Application. However, the construction of “customer interface” that must be supported by the written description of the Original Application is the construction given by the district court for the term as used in the ’658 and ’400 patents. That the Original Application may support a narrower construction of “customer interface” as a display on the vending machine does not mean that the Original Application supports the broader construction of a “customer interface” as an interface located on the customer’s laptop (remote from the vending machine). “[T]he invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” Vas-Cath, 935 F.2d at 1564 (emphasis in original). Since the Original Application does not support a “customer interface” on a customer laptop, the asserted claims are not entitled to the effective filing date of the Original Application. Because the asserted claims are limited to the filing date of the CIP Application, June 15, 2000, they are anticipated by the MobileStar Network.

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Editor’s Note

In Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859, 870-71 (Fed. Cir. 2010), the Federal Circuit extended the burden-of-proof reasoning from PowerOasis to a case involving the written-description support for claims in a continuation application, i.e., an application in which the claim language had changed but the supporting written disclosure had not.
Synthes USA, LLC v. Spinal Kinetics, Inc.
734 F.3d 1332 (Fed. Cir. 2013)

O’Malley, Judge:

Synthes USA, LLC and DePuy Synthes Products, LLC (collectively “Synthes”) appeal from a jury verdict finding that Spinal Kinetics, Inc. (“SK”) did not infringe claims 29-31 (“asserted claims”) of U.S. Patent No. 7,429,270 and that the claims were invalid for lack of written description. … For the reasons below, we affirm the jury verdict of invalidity for lack of written description … .

I. Background

A. The ’270 Patent and Accused Devices

Synthes filed this action alleging that SK’s M6-C and M6-L intervertebral implants infringed claims 29-31 of the ’270 patent. The ’270 patent originated from a German language PCT application filed on April 14, 2003. The asserted claims were added by amendment on February 19, 2008. The ’270 patent is directed to an “Intervertebral Implant,” which is a prosthetic device designed to replace a diseased or degenerated disc located between adjacent vertebrae of the human spine:

A healthy disc (depicted below) has a fibrous, outer band called the annulus fibrosus, which surrounds a central, gel-like substance called the nucleus pulposus:

A natural disc provides shock-absorbing functions and helps maintain proper spacing, stability, and motion within the spine. Artificial discs attempt to replace some or all of these functions. Claim 29, the independent claim from which claims 30 and 31 depend, provides:

29. An intervertebral implant for implantation between an upper and lower vertebrae, the implant having a central axis, the implant comprising:
a first substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the upper vertebra;
a second substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the lower vertebra;
a third plate operatively coupled to the first bone contacting plate, the third plate including a plurality of openings;
a fourth plate operatively coupled to the second bone contacting plate, the fourth plate including a plurality of openings;
a central part substantially located between the third and fourth plates, the central part including a flexible core and a fiber system, wherein the core is substantially cylindrical and includes a top surface and a bottom surface, the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate, and wherein the fiber system at least partially surrounds the core, and is at least partially received within the plurality of openings formed in the third and fourth plates so that the fiber system is joined to the third and fourth plates; and
an elastic sheathing body at least partially surrounding the fiber system and the core, and connected to the third and fourth plates.

‘270 patent, col. 8, ll. 19-48.

Claim 30 requires that the first and second bone contacting plates recited in claim 29 be made from titanium or titanium alloy. Claim 31 requires the fiber system recited in claim 29 to be constructed of an “ultra high molecular weight polyethylene material.” According to Synthes, claims 30 and 31 stand or fall with claim 29. The main features of claim 29 are depicted in Figures 3 and 4 of the ‘270 patent:

SK manufactures the M6-C (cervical) and M6-L (lumbar) discs in California and sells them abroad. The United States Food and Drug Administration has not approved the M6 devices for sale in this country. The M6-C and M6-L are depicted below:

M6-C
M6-L

Except for the shape of the cores, the M6-C and M6-L are identical for purposes of this litigation.

B. Proceedings Below

During the course of the litigation, the district court construed a number of terms contained in claim 29 of the '270 patent. Of particular relevance to the current appeal is the court’s construction of the phrase “the third plate including a plurality of openings.” SK argued that “plurality of openings” should be limited to grooves on the circumference of the claimed cover plates. SK’s argument was predicated on its contention that the written description of the '270 patent does not describe a structure with holes or slots in the cover plates, but only describes grooves on the circumference of the cover plate that radially penetrate into the lateral surface of the plate. Those grooves are depicted as element 18 in Figure 2 of the '270 patent:

Synthes, on the other hand, contended that the claim was not so limited, and urged the court for a broader construction: “a third plate including two or more openings.” While the district court did not adopt Synthes’ construction wholesale, it did side with Synthes regarding the breadth of the phrase and construed it as “the third plate including two or more openings to allow the fiber system to be joined or anchored to that plate.” The court concluded that claim 29 requires openings in the cover plates, or third and fourth plates, which make it possible for the claimed fiber system to be joined or anchored to the plates.

The importance of the “plurality of openings” limitation to Synthes’ infringement case is evident when viewed in light of the accused devices. SK devices do not employ peripheral grooves, but instead use slots, or openings, on the cover plates. The M6 lumbar device uses trapezoidal slots, while the cervical device uses elongated circle slots:
According to SK, Synthes amended the application that led to the ’270 patent during prosecution to add claims 29–31 only after the M6 devices were on the market and Synthes was advised that SK’s M6 devices were a significant improvement in the technology.

After the court construed the disputed terms of the patent, it entertained motions for summary judgment. The district court ... denied Synthes’ motion to dismiss SK’s written description ... defense[]. The parties proceeded to trial on the remaining issues. After hearing all of the evidence, followed by four days of deliberation, the jury concluded that SK’s M6 devices did not infringe the asserted claims of the ’270 patent and that SK proved by clear and convincing evidence that claim 29, and consequently claims 30 and 31, were invalid for a lack of written description support.

...  

II. Discussion

The district court found substantial evidence supported the jury verdict that the term “plate including a plurality of openings” lacked written description support, rendering the asserted claims invalid. ... We agree with the district court ... .

...  

The district court, at Synthes’ urging, broadly construed the phrase “third plate including a plurality of openings,” which appears in claim 29. The relevant claims, moreover, include broad language added during prosecution. Synthes amended the application that became the ’270 patent to add the concept of “openings” in claim 29 almost five years after the application was originally filed, and after SK’s M6 devices were already on the market. The original disclosure claimed and disclosed a plurality of grooves and a plurality of channels, but did not describe “openings” generally. While broadening claims during prosecution to capture a competitor’s products is not improper, the written description must support the broadened claims. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 n.2 (Fed. Cir. 2004) (“[I]t is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor’s products, as long as the disclosure supports the broadened claims.”) (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988)). After hearing the testimony of SK’s expert, Dr. Lee, and its research and development manager, Mr. Koske, indicating that the as-filed disclosure did not demonstrate possession of an intervertebral implant that employed any sort of openings anywhere on the cover plates, the jury deter-
mined that the ’270 patent was invalid under § 112, paragraph 1. As the district court did before us, we find that substantial evidence supports that conclusion.

Section 112 requires a patentee to provide a written description that allows a person of skill in the art to recognize that the patentee invented what is claimed. See Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citing Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991)). “[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” Id. Determination of whether a patent satisfies the written description requirement is a question of fact. Id. (citing Capon v. Eshar, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005)). The “level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” Id.

Synthes contends that the jury’s verdict of invalidity for a lack of adequate written description was not supported by substantial evidence. Synthes asserts that the ’270 patent’s written description does not limit the claimed “plurality of openings” to peripheral grooves. Synthes next argues that the testimony and evidence presented by SK via its expert and fact witnesses regarding the “plurality of openings” limitation did not support the jury’s verdict. Synthes also disputes the district court’s post-trial conclusion that SK produced evidence demonstrating that the field of intervertebral implants was sufficiently unpredictable such that a disclosure of one species of openings would not be enough to claim the entire genus. We disagree on all counts.

The ’270 patent’s written description, filed on April 14, 2003, discloses that the fiber system may be anchored by various means. The written description then discloses a series of examples of how the fiber system may be anchored on the cover plates, i.e., third and fourth plates. All of these examples employ “grooves,” not slots or openings on the plates. Claims 29-31 recite a “plurality of openings” used to “join” or “anchor” the fiber system to the cover plates, which Synthes contends supports any type of openings located anywhere on the plates. The written description, however, never discloses anything broader than using grooves to anchor the fiber system to the cover plates.

The parties appear to agree that “grooves” are a species of “opening,” but do not agree that “grooves” constitute an adequate disclosure to claim all openings that may be used in the cover plates to anchor the fiber system. In other words, the jury was asked to determine whether the written description disclosure of “grooves” “reasonably convey[ed] to those skilled in the art that the inventor had possession of [an intervertebral implant that could utilize any sort of opening located anywhere on the cover plates to anchor the fiber system] as of the filing date.” Ariad, 598 F.3d at

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3 Congress recently changed the language and structure of 35 U.S.C. § 112. See Leahy-Smith America Invents Act, Pub. L. No. 112-29. Those amendments made no changes of relevance to this appeal.
1351. The jury did not believe so and, when all reasonable inferences are drawn in favor of the jury verdict, we must affirm that decision.

SK presented testimony regarding the plurality of openings limitation via its expert, Dr. Lee, and its research and development manager, Mr. Koske. Dr. Lee testified, based on his experience in designing total disc replacements, that a person of ordinary skill in the art would not believe that Synthes had possession of an intervertebral implant utilizing openings located anywhere on the cover plates based on the disclosure of peripheral grooves in the written description. In particular, Dr. Lee testified that: (1) based on his reading of the written description, the disclosure of peripheral grooves would not disclose openings located anywhere on the plates; (2) there are significant biomechanical property differences between using peripheral grooves and interior slots; and (3) when the fiber system is attached via peripheral grooves, the distance of the fibers to the central axis is limited, but when openings are used anywhere on the cover plates, the fibers are not so limited in proximity to the central axis of the device.

Mr. Koske buttressed Dr. Lee’s testimony that, based on his direct experience developing the accused products, the process of moving from peripheral grooves to internal slots is not a simple substitution, but a careful and timeconsuming task. Mr. Koske, for example, testified that SK rejected early prototypes that used peripheral grooves on the cover plates. Mr. Koske was presented with a photograph of various SK devices, which he described as a “design time line” of M6 devices. Mr. Koske then testified that the “early prototypes” with peripheral grooves were repeatedly rejected. Mr. Koske’s testimony and attendant trial exhibits demonstrated that SK’s development process from the peripheral grooves to the commercial products took months of work.

Mr. Koske also testified that SK had to overcome technical hurdles through its development process, one of which was to reduce wear on the device. Because the devices may be used on people in their 20s and 30s and would be required to last a lifetime, wear was an important consideration in design choice. In particular, Mr. Koske stated that the shape of the slots on the cover plates played a role in wear reduction. Mr. Koske explained that, because the metal cover plates are very thin, if the slots were too large, it would increase the risk of the cover plates breaking. SK, therefore, had to determine the precise size and location of the slots to ensure that the cover plates used as little metal as possible, reduced fiber wear, and still performed all of the necessary functions of the device.

Taken together, Mr. Koske’s testimony is at least circumstantial evidence that it would not be evident that peripheral grooves on the cover plates would disclose to skilled artisans that internal slots would serve the same function. Mr. Koske’s testimony and the exhibits used during it, coupled with Dr. Lee’s testimony, provided ample evidence for the jury to conclude that the written description did not support the broad claim limitations in the asserted claims.

Synthes contends that the difference Dr. Lee identified is “specious.” Rather than provide contrary evidence, however, Synthes points to a very curt cross-examination wherein Dr. Lee agreed with Synthes’ counsel that deeper grooves—or grooves cut deeper into the cover plates—might reduce the distance of the fibers
from the central axis. Synthes’ cross-examination, however, does not address any of Dr. Lee’s other points. And, even if Synthes’ cross-examination of Dr. Lee would allow us to draw a different conclusion, so long as substantial evidence supported the jury’s verdict, we must affirm its decision.

Synthes also attempts to minimize the relevance of Mr. Koske’s testimony by contending that his testimony was not directed to differences between using peripheral grooves and internal slots. Mr. Koske, however, testified that the shape and size of the slots, and the optimization of those slots, were important design considerations. And, while Synthes is correct that Mr. Koske did not use “magic words” to explain why SK chose internal slots instead of peripheral grooves, the jury was free to draw its own conclusions from Mr. Koske’s testimony. Coupled with Dr. Lee’s expert testimony on the “plurality of openings” limitation, the jury’s verdict that a person skilled in the art would not understand that a disclosure of peripheral grooves would teach that any and all openings on the cover plates are disclosed is supported by substantial evidence.

The jury was entitled to rely on the above testimony and evidence to conclude that the ’270 patent’s written description does not support the broad plurality of openings limitation. Written description is a factual question, and whether the requirement is met “varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” Ariad, 598 F.3d at 1351. While the predictability of the “aspect at issue” is not the dispositive factor in determining whether the written description requirement is satisfied, the district court relied on it, and Synthes strenuously disputes the district court’s conclusion. We, thus, briefly address it. Id.

Synthes frames the “aspect at issue” as “the shape and locations of openings used to join or anchor a fiber system to a plate.” As chronicled above, Dr. Lee testified that the difference between peripheral grooves and internal slots would present significant engineering and design choices and maintained that the differences between the two designs would present substantial biomechanical differences. Mr. Koske also explained that SK itself began its development process with peripheral grooves and ended with internal slots. Mr. Koske’s testimony also indicated that the shape of the internal slots was an important design choice that required testing to account for wear on the fiber system. All of this testimony was unrebutted.

Based on this evidence, the jury was free to conclude that, because the ’270 patent’s written description does not disclose anything other than peripheral grooves, there would be significant biomechanical differences between using peripheral grooves and internal slots. The jury was also free to determine that SK’s skilled artisans made a specific design choice to change its first prototype with peripheral grooves to specifically shaped and located internal slots. And, the jury was free to conclude, based on the evidence, that the use of internal slots for these devices was not predictable.

SK is correct that a “disclosure of a species may be sufficient written description support for a later claimed genus including that species.” Bilstad v. Wakalopulos, 386 F.3d 1116, 1124 (Fed. Cir. 2004) (emphasis added). But, as we stated in Bilstad:
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[i]f the difference between members of [a species] is such that [a] person skilled in the art would not readily discern that other [species] of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus. *Id.* at 1125. In other words, predictability is a factual issue judged on a case-by-case basis. Here, SK presented its case to the jury, and the jury inferred that, in the field of intervertebral implants, the disclosure of peripheral grooves does not adequately demonstrate possession of the entire genus of possible openings. Because the jury’s verdict is supported by substantial evidence, we must defer to that finding.

Synthes contends that, because we remarked in *Bilstad* that the “mechanical world” is a “fairly predictable field,” SK had to satisfy a heightened burden to demonstrate unpredictability. See *Bilstad*, 386 F.3d at 1126. First, SK had no higher burden than providing clear and convincing evidence that the ’270 patent does not satisfy the written description requirement on the “plurality of openings” limitation. Second, while we did state in *Bilstad* that the mechanical field was “fairly predictable,” we did not hold that all inventions that may be characterized as “mechanical” allow claiming a genus based on disclosure of a single species.

As we noted in *Ariad*, there are no “bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.” *Ariad*, 598 F.3d at 1351. Indeed, factual inquiries will, at times, create confounding results. But, whatever inconsistencies may appear “to exist in the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.” *Id.* at 1352. That is precisely the situation here. After hearing all of the testimony and evidence, the jury resolved the facts in favor of SK and determined that it had met its burden of proving by clear and convincing evidence that the ’270 patent did not satisfy the written description requirement. Again, we are not entitled to disturb that finding when there was substantial evidence to support it.

... Taranto, Judge, dissenting:

In my view, Spinal Kinetics failed as a matter of law to show, by clear and convincing evidence, that asserted claims 29-31 of Patent No. 7,429,270 are invalid for inadequacy of the written description. In particular, Spinal Kinetics offered no clear and convincing proof that the difference between the “openings” of the claims and the grooves of the written description is one that (in the eyes of skilled artisans) has any effect, let alone an effect that is difficult to predict, on fulfillment of the identified purposes of the claims at issue. ... I therefore respectfully dissent from the majority’s affirmance of the judgment that the patent claims are invalid.

... A

The written-description challenge in this case is to structural claim language that is broader than the specific embodiments disclosed in the written description.
This is not a case—such as some cases involving genetic or chemical inventions—in which the claim language at issue is functional rather than an identifier of structure. See, e.g., Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349-50 (Fed. Cir. 2010); Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997). Nor is it a case in which the claim language includes details that do not appear in the written description. See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1327 (Fed. Cir. 2000). The written-description question here is the familiar one involving whether the claim language is simply too broad given the disclosure—notwithstanding that claim language may be and commonly is broader than described embodiments, as it identifies what aspects of the disclosed embodiments matter. See In re Rasmussen, 650 F.2d 1212, 1215 (CCPA 1981) (“[T]hat a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment.”); Ronald Slusky, Invention Analysis and Claiming: A Patent Lawyer’s Guide at 32-33 (2007) (discussing claim drafting process of identifying what features of embodiment matter).

In a case like this one, the written-description requirement must focus on whether the way in which the (broader) claim term differs from the (narrower) disclosure is pertinent to fulfilling the identified purposes of the claims at issue. More specifically, for a challenger to prove insufficiency of the written description to support the claim language, the challenger must identify the respect in which the claim language differs from the disclosed embodiments. At a minimum, the challenger must then demonstrate that, in the eyes of a relevant skilled artisan, that particular difference has a material effect on whether the product or process would achieve the aims of the claims at issue, with materiality of the effect not the same as non-obviousness but related to predictability (this case requiring no further definition of that relation).¹

It is commonly true, of course, that a skilled artisan has to make some judgments when seeking to implement the patent, whether it is the described embodiments or an undescribed embodiment of the broader claim that the artisan is proceeding to make and use. If those judgments are sufficiently unguided by the written description, unknown to a skilled artisan, or uncertain (requiring undue experimentation), at least an enablement problem may arise—though there is no enablement challenge here. What is critical for present written-description purposes is this: if there is materially the same range of implementation judgments for the described embodiments and the broader claim—such as, here, how many openings/grooves to have, their shape, how close to the center and far from the periphery they would locate the fibers passing through—the need for such judgments is irrelevant to the written-description question. What matters is only the particular difference between the narrower embodiments and broader claims.

¹ A patent’s written description may describe more than one purpose or problem to be solved, and a particular claim may not address all of them. See, e.g., Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc). The written-description analysis of a particular claim must focus on the purposes and problems relevant to that particular claim.
Recognizing the burden of proof carried by the challenger, this approach implements the Ariad formulations: whether the inventor “possessed the claimed invention,” or “actually invented the invention claimed.” 598 F.3d at 1351, 1355-56. If the challenger does not make the showing identified above, the relevant skilled artisan will understand that, by expressly describing certain embodiments, the inventor possessed the more broadly claimed invention, because the differences are immaterial to what the inventor invented. See In re Peters, 723 F.2d 891, 893 (CCPA 1983) (reversing claim rejections that were based on a difference between the broader claim terms and the narrower disclosure, because “[m]ost importantly, one skilled in the art would readily understand that in practicing the invention [the difference] is unimportant”). If the challenger has made the identified showing, the relevant skilled artisan will understand that the inventor had not (based on the disclosure) addressed issues of consequence to fulfilling the invention’s purpose, and so did not possess in full the broadly claimed invention. See Ariad, 598 F.3d at 1353 (“Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of ‘invention’—that is, conceive of the complete and final invention with all its claimed limitations.”).

At the same time, this approach aligns with a critical role of the written-description requirement in a case involving a question of breadth. In such a case, the requirement serves to prevent an inventor from acquiring exclusivity rights over potential products or processes that present problems in achieving the invention’s aims that he or she has not solved. See Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (“attempt[s] to preempt the future before it has arrived” are “not in compliance with the description requirement”). It thus confines patents to the problems the inventor solved and leaves to other people the solutions they identify that the inventor did not.

B

In this case, Spinal Kinetics failed to present the proof required to show an insufficient written description. The difference between the claimed “openings” and the disclosed “grooves” is simply that, for a groove, the space remains open at the perimeter whereas, for an “opening,” it need not be: “opening” covers slots wholly interior to the outer boundary of the plate. But Spinal Kinetics did not prove that that difference—potential closure at the perimeter—had any effect on the ability of the invented implants to fulfill their purpose.

The evident role of the grooves is to prevent sideways movement of the fibers, along the perimeter of the plate, as they hold the components of the implant together. See ’270 patent at col. 3, ll. 27-30 (“By guiding the fibres in the grooves the fibre system can be so anchored on the cover plates, that in the case of tensile forces acting on the fibres no slipping of the fibres on the lateral sides is possible.”) (emphasis added). Nothing in Spinal Kinetics’s proof showed that closing the space at the perimeter affects that function (let alone in an unpredictable way). More generally, nothing in Spinal Kinetics’s proof showed that the difference between grooves and interior openings was material to the working of the claimed device. The two witnesses on which Spinal Kinetics relies for its written-description challenge are its expert, Dr. Lee, and its Research and Development Manager, Mr. Koske. Neither
they, nor the documents on which they relied, showed (by clear and convincing evidence) how the way in which “openings” differ from “grooves” makes any material difference to the working of the claimed device.

Dr. Lee’s key testimony was his statement that “the stress or strain on the fibers” is affected by whether the fibers pass through the plate near the center or near the perimeter. But, decisively, the distance from the center (or perimeter) is not the respect in which “openings” differ from “grooves.” Whether the space at the perimeter remains open (as with grooves) or closed (as with openings) plays no role in determining how far from (or near to) the center the fibers pass through the plate: if a groove extends deep toward the center, the fibers will pass through the plate there, just as they will if openings are placed at that location. Dr. Lee’s testimony, not addressing the difference between openings and grooves, is irrelevant to the analysis.

Nothing else Dr. Lee said makes up for the irrelevance of the foregoing testimony. He testified that he could not find the word “openings” in the specification, but that is itself of no importance: the written-description requirement is about support in substance, not about labels. Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 967-68 (Fed. Cir. 2006). Dr. Lee also stated that there was a “significant difference *** in biomechanical properties” between the broader claim term and the narrower disclosure. But without the eventual identification of what difference in properties he meant, that sentence is entirely a conclusory opinion, which is insufficient to meet a burden of proving facts by clear and convincing evidence. See, e.g., Active Video Networks, Inc. v. Verizon Comm’ns, Inc., 694 F.3d 1312, 1327, 1330-31 (Fed. Cir. 2012); Krippelz v. Ford Motor Co., 667 F.3d 1261, 1269 (Fed. Cir. 2012); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 294 (Fed. Cir. 1985). It was only the distance-from-center testimony discussed just above that gave any concrete factual content to the otherwise-conclusory assertion, but that basis, as shown, is irrelevant to the required analysis.

Mr. Koske likewise did not present the required proof, either through his testimony or through the exhibits about which he testified. That evidence established that, at one point, Spinal Kinetics had one or more prototypes with grooves (and many other features) and that it eventually settled on a design that had interior openings (and many other features). But nowhere did Mr. Koske testify, and nowhere do the exhibits show, that the earlier prototypes were rejected because they had grooves as opposed to interior openings or that the Spinal Kinetics product development process focused on that difference. The evidence identifies “technical hurdles” involving whether to use fibers or adhesive to anchor the fiber system to the cover plates, and concerns about what shape the interior openings should be to preserve disc strength, but none of the evidence addresses the differences between grooves and interior openings in relation to those or any other issues. In none of the testimony of Mr. Koske or the documents cited by Spinal Kinetics, or the evidence cited by the majority opinion is there any indication about how much if any experimentation or study Spinal Kinetics did to choose between interior openings and grooves or about any material challenges encountered when considering use of interior openings versus grooves (there can be a plurality of either, and each can cause
the fiber location to be almost anywhere in the plate). In my view, this is not clear and convincing evidence.

Spinal Kinetics thus failed to establish the importance of the openings/grooves difference. And that conclusion is reinforced indirectly by the patent itself—specifically, by the fact that the written description is not actually limited to using grooves for the fibers. The majority states that the specification “discloses a series of examples of how the fiber system may be anchored on the cover plates” and that “[a]ll of these examples employ ‘grooves,’ not slots or openings on the plates.” But the specification, while reciting grooves in some of the examples it gives for how “anchoring of the fibres on the cover plates can be carried out,” includes other examples that are described without any mention of grooves at all. One separately stated example simply calls for “adhering the fibre system on the cover plates,” while another calls for join the plates “in a form-locking manner.” Thus, grooves are not part of all of the anchoring embodiments disclosed in the ’270 patent.

... 

AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.

759 F.3d 1285 (Fed. Cir. 2014)

Lourie, Judge:

AbbVie Deutschland GmbH & Co. [and others] appeal from the final judgment[...]. In the infringement action, patent owner AbbVie sued Janssen Biotech, Inc. and Centocor Biologics, LLC (collectively “Centocor”) for infringement of ... U.S. Patent No. 6,914,128 ... and ... U.S. Patent No. 7,504,485. ...

After a trial on validity in the infringement action, the jury determined that all of the asserted claims were invalid on the grounds of written description, enablement, and obviousness. The district court denied AbbVie’s post-trial motions ... .

... 

We conclude that ... record evidence sufficiently supported the jury verdict that the asserted claims lacked adequate written description under 35 U.S.C. § 112, ¶ 1 (2006). ... Because all of the asserted claims are invalid for failing to satisfy the written description requirement, we need not address AbbVie’s validity arguments concerning enablement or its procedural challenges to the district court’s obviousness judgments. ...

Background

The technology in these appeals involves antibodies that are useful for treating diseases. An antibody is a protein that binds to a foreign substance, called an antigen, to facilitate its removal from the body. The portion of the antigen that binds to the antibody is called the epitope. Each antibody consists of four chains of amino acids, two identical heavy chains and two identical light chains, which are folded into a three-dimensional structure. Each of the heavy and light chains consists of a constant region and a variable region. The variable region is the portion of the antibody in its three-dimensional structure that binds to the antigen and each variable region has three complementarity determining regions (“CDRs”) that interact close-
ly with the epitope of the antigen. Among human antibodies, the variable region of the heavy chains can be divided into seven families, $V_{H1}$ to $V_{H7}$; and the variable region of the light chains can be divided into two classes: Kappa and Lambda. The binding affinity of an antibody to an antigen can be measured by $k_{off}$, the rate at which the antigen dissociates from the antibody after binding, wherein a smaller $k_{off}$ value represents a tighter binding.

AbbVie owns the ’128 and ’485 patents, directed to fully human antibodies that bind to and neutralize the activity of human interleukin 12 (“IL-12”). IL-12 is a signaling protein secreted by the human body, the over-production of which can cause psoriasis and rheumatoid arthritis. Because the human body does not typically make antibodies to neutralize its own proteins, it does not produce IL-12 antibodies naturally. Antibodies from a non-human species often lack the desirable safety profile of a drug because non-human antibodies can cause adverse immune reactions in human patients. Researchers therefore sought to genetically engineer fully human IL-12 antibodies that are derived from human DNA and thus less likely to trigger an immune response.

The techniques that could be used to develop a fully human IL-12 antibody have included phage display and transgenic mice. AbbVie developed its IL-12 antibodies using phage display, which involved creating a large library of human DNA fragments and screening for those fragments that encoded an antibody fragment with IL-12 binding affinity. AbbVie identified a lead, through screening, that it named “Joe-9,” which had the ability to bind to and neutralize the activity of IL-12, albeit with low affinity. In order to improve IL-12 affinity, AbbVie introduced mutations to the CDRs of Joe-9 and identified an improved antibody that it named “Y61.” AbbVie then used site-directed mutagenesis to alter individual amino acids at selected positions in Y61 and generated additional antibodies, among which an antibody that it named “J695” showed a significant increase in IL-12 binding and neutralizing activity.

The ’128 and ’485 patents share the same written description and both claim priority from a provisional application filed in 1999. The patents describe the amino acid sequence of about 300 antibodies having a range of IL-12 binding affinities. Joe-9, the initial lead, has $V_{H3}$ type heavy chains and Lambda type light chains. Because the IL-12 antibodies described in the patents were all derived from Joe-9, they all have $V_{H3}$ type heavy chains and Lambda type light chains. The described antibodies share a 90% or more amino acid sequence similarity in the variable regions. And over 200 of those antibodies were generated by site-directed mutagenesis of Y61 and thus differ from Y61 by only one amino acid and share a 99.5% sequence similarity in the variable regions.

The ’128 and ’485 patents also teach that “the amino acid sequence identity within the entire $V_{H3}$ family is high,” which “results in certain amino acid residues being present at key sites in the CDR and framework regions of the VH chain,” and thus that “other $V_{H3}$ family members could also be used to generate antibodies that bind to human IL-12.” ’128 patent, col. 41, ll. 15-17, 27-31, 54-57. The patents similarly teach that “other $V_{\Lambda 1}$ [Lambda 1] family members may also be used to generate antibodies that bind to human IL-12.” Col. 42, ll. 5-8. The patents, how-
ever, do not describe any IL-12 antibody having heavy chains outside of the V\textsubscript{H3} family or light chains outside of the Lambda family.

The claims of the ’128 and ’485 patents at issue in these appeals define the claimed antibodies by their function, i.e., IL-12 binding and neutralizing characteristics, rather than by structure. Claim 29 of the ’128 patent is representative and reads as follows:

29. A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and dissociates from human IL-12 with a \( k_{\text{off}} \) rate constant of \( 1 \times 10^{-2} \) s\(^{-1} \) or less, as determined by surface plasmon resonance.

Claims 30 and 32 likewise require the \( k_{\text{off}} \) rates to be \( 1 \times 10^{-4} \) s\(^{-1} \) or less and \( 1 \times 10^{-3} \) s\(^{-1} \) or less, respectively. Claim 64 is directed to a pharmaceutical composition comprising the functionally claimed antibody. Claim 11 of the ’485 patent similarly defines the claimed antibody by its IL-12 binding profile.

Centocor developed its human IL-12 neutralizing antibody drug marketed under the brand name “Stelara” using the transgenic mice technology, which involved mice that are genetically modified with human antibody genes and capable of producing human antibodies when exposed to an antigen such as IL-12. Stelara has V\textsubscript{H5} type heavy chains, not V\textsubscript{H3}; and Kappa type light chains, not Lambda; and about 50% sequence similarity in the variable regions as compared to the Joe-9 antibodies described in the ’128 and ’485 patents, which is significantly lower than the 90% sequence similarity shared among the Joe-9 antibodies. The [FDA] approved Stelara [for sale] in 2009.

On August 10, 2009, AbbVie filed an infringement action against Centocor … asserting that Stelara infringed the ’128 and ’485 patents. …

After construing the claims, the court entered summary judgment that Centocor infringed claims 29, 32, and 64 of the ’128 patent and claim 11 of the ’485 patent. The parties then stipulated that claim 30 of the ’128 patent was also infringed.

The validity of the asserted claims was tried before a jury in the infringement action. …

Centocor raised four invalidity defenses on the bases of written description, enablement, obviousness, and anticipation by prior invention. To support its invalidity challenges under § 112, Centocor presented evidence seeking to establish that the antibodies described in AbbVie’s patents were not representative of other members of the functionally claimed genus, which included Stelara. Centocor presented expert
testimony that the antibodies described in the patents were structurally similar, but that they differed from Stelara in many respects, set out [above].

Among the five structural distinctions, the distinction on epitope binding sites was based in part on a crystal structure of J695 binding to IL-12, which was obtained from AbbVie during discovery. Centocor informed the jury that the PTO did not have that information when it issued the patents.

The jury ... determined that each of the asserted claims was invalid for lack of an adequate written description ...

Discussion

Whether a patent claim is supported by an adequate written description is a question of fact, and we review a jury’s factual determination relating to compliance with the written description requirement for substantial evidence. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1355 (Fed. Cir. 2010) (en banc). Furthermore, patents are presumed to be valid, and overcoming this presumption requires clear and convincing evidence. 35 U.S.C. § 282; Microsoft Corp. v. i4i Ltd., 131 S. Ct. 2238, 2243 (2011).

AbbVie argues that each of the asserted claims is limited to a small genus of antibodies that are rare and difficult to obtain and that its patents describe a representative number of antibodies commensurate with the scope of the claims. AbbVie maintains that the disclosed antibodies reflect the variation of the entire genus because they cover the full range of the claimed feature, the k_{off} rate. AbbVie also asserts that it disclosed the amino acid sequence of all known species covered by the claims except for Stelara and that its patents were not required to provide individual written description of an infringing product. AbbVie argues that Centocor incorrectly seeks to distinguish Stelara on the basis of unclaimed structural features that are legally irrelevant and have no correlation to the claimed k_{off} rate. AbbVie maintains that even if the structural variations are relevant at all, AbbVie’s patents disclose a variety of amino acid sequences of the CDRs of its antibodies.

Centocor responds that the jury verdict of invalidity for inadequate written description is supported by substantial evidence. Centocor maintains that AbbVie’s patent disclosure is limited to a family of closely related, structurally similar antibodies that are all derived from Joe-9, whereas AbbVie’s functionally defined claims cover antibodies having widely varying structures including Stelara. Centocor therefore argues that the antibodies disclosed in AbbVie’s patents are not representative of the entire genus. Centocor also responds that AbbVie’s argument that structural differences are legally irrelevant is contrary to the law of written description. Centocor contends that the functional requirement of the claims, i.e., the k_{off} rate, is dependent on the structure of the antibody and that AbbVie’s evidence purporting to show the disclosure of representative species is irrelevant.

We agree with Centocor that substantial evidence supports the jury verdict that the asserted claims are invalid for lack of an adequate written description. The written description requirement has long been part of our patent law. It is provided for
in the statute, and drafters of patent applications know that they must describe their inventions as well as disclose how to enable their use. This court en banc held in *Ariad* that the written description requirement is separate from the enablement requirement. *Ariad*, 598 F.3d at 1344. We also explained that the requirement for an adequate written description serves a different purpose from that of the claims. *Id.* at 1347 (“Claims define and circumscribe, the written description discloses and teaches.”).

The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (“The[] requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification ***.”); *O’Reilly v. Morse*, 56 U.S. 62, 120-21 (1853) (“The evil is the same if he claims more than he has invented, although no other person has invented it before him. He prevents others from attempting to improve upon the manner and process which he has described in his specification and may deter the public from using it.”).

We have explained that “requiring a written description of the invention plays a vital role in curtailing claims *** that have not been invented, and thus cannot be described.” *Ariad*, 598 F.3d at 1352. “[T]he purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.’” *Id.* at 1353-54 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004)). We have held that the written description requirement with respect to particularly claimed subject matter is met if the specification shows that the stated inventor has in fact invented what is claimed, that he had possession of it. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). We have stated that possession is shown by disclosure in the patent. *Ariad*, 598 F.3d at 1351 (“*[T]he hallmark of written description is disclosure *** the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.”).

One particular question regarding the written description requirement has been raised when a genus is claimed but the specification only describes a part of that genus that is insufficient to constitute a description of the genus. In *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), we held that a genus of mammalian insulin DNA was not supported by a description of rat insulin DNA. Without doubt, rats are different from other mammals, including humans. A description of one does not describe or show that one has invented the whole genus of mammals. Whether the written description requirement for a genus is met by a particular disclosure depends upon the facts. *Ariad*, 598 F.3d at 1351. This case presents such a question. The jury found that the requirement was not met, and we agree.
“For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.’” Id. (quoting Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). When a patent claims a genus using functional language to define a desired result, “the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.” Id. at 1349. We have held that “a sufficient description of a genus *** requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” Id. at 1350 (quoting Eli Lilly, 119 F.3d at 1568-69).

Here, the claimed invention is a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen. AbbVie’s expert conceded that the ‘128 and ‘485 patents do not disclose structural features common to the members of the claimed genus. The question therefore is whether the patents sufficiently otherwise describe representative species to support the entire genus.

One factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it. That is the case here.

It is important not to take the analogy of a plot of land too far in thinking of written description issues because, even if one builds a house only in one corner of the plot, one may still own the whole plot. One describes a plot of land by its furthest coordinates, in effect drawing a perimeter fence around it. That may be akin to the function of patent claims to particularly point out and distinctly circumscribe the outer boundaries of a claimed invention. With the written description of a genus, however, merely drawing a fence around a perceived genus is not a description of the genus. One needs to show that one has truly invented the genus, i.e., that one has conceived and described sufficient representative species encompassing the breadth of the genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus. See Ariad, 598 F.3d at 1353 (The written description requirement guards against claims that “merely recite a description of the problem to be solved while claiming all solutions to it and *** cover any compound later actually invented and determined to fall within the claim’s functional boundaries.”).

Here, the jury heard ample evidence that AbbVie’s patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus. All of the antibodies described in AbbVie’s patents were derived from Joe-9 and have V\text{H\text{3}} type heavy chains and
Lambda type light chains. Although the described antibodies have different amino acid sequences at the CDRs, they share 90% or more sequence similarity in the variable regions and over 200 of those antibodies differ from Y61 by only one amino acid. The patents describe that other $V_{H}3$/Lambda antibodies may be modified to attain IL-12 binding affinity. However, the patents do not describe any example, or even the possibility, of fully human IL-12 antibodies having heavy and light chains other than the $V_{H}3$ and Lambda types.

In contrast, Centocor’s Stelara, which falls within the scope of the claimed genus, differs considerably from the Joe-9 antibodies described in AbbVie’s patents. Stelara has $V_{H}5$ type heavy chains and Kappa type light chains. The variable regions of Stelara only share a 50% sequence similarity with the Joe-9 antibodies, which is far lower than the 90% sequence similarity shared among the Joe-9 antibodies described in AbbVie’s patents. Centocor’s expert testified that antibodies with 80% sequence similarity to J695 could bind to completely different antigens, thus illustrating the significant structural differences between Stelara and the Joe-9 antibodies and the unpredictability of the field of invention. Centocor also presented evidence of other differences between Stelara and the Joe-9 antibodies, such as CDR length and epitope binding site.

Because each of the asserted claims encompasses both the Joe-9 antibodies and the allegedly infringing Stelara, the claimed genus covers structurally diverse antibodies. The ’128 and ’485 patents, however, only describe species of structurally similar antibodies that were derived from Joe-9. Although the number of the described species appears high quantitatively, the described species are all of the similar type and do not qualitatively represent other types of antibodies encompassed by the genus. See Ariad, 598 F.3d at 1351 (“[N]o bright-line rules govern[] the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.”).

It is true that AbbVie’s patents need not describe the allegedly infringing Stelara in exact terms. Eli Lilly, 119 F.3d at 1568 (“[E]very species in a genus need not be described in order that a genus meet the written description requirement.”). However, the patents must at least describe some species representative of antibodies that are structurally similar to Stelara. On review of the record, there is no evidence to show any described antibody to be structurally similar to, and thus representative of, Stelara. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as Stelara.

Instead, AbbVie argues that structural differences are legally irrelevant and inappropriately attempts to rely on the $k_{off}$ rates to show representativeness. The $k_{off}$ rate is merely a desired result, rather than the actual means for achieving that result. The asserted claims are directed to new compositions, i.e., fully human antibodies having desired IL-12 binding characteristics. It is undisputed that the structure of the antibody determines its antigen binding characteristic. In order to demonstrate that it has invented what is claimed, AbbVie’s patents must adequately describe representative antibodies to reflect the structural diversity of the claimed genus. See Eli Lilly, 119 F.3d at 1568 (“[N]aming a type of material generally known to exist, in the
absence of knowledge as to what that material consists of, is not a description of that material.”); *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (“Claiming all DNA[s] that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.”).

Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus. *Ariad*, 598 F.3d at 1351 (“[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”); see also *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011) (noting the technical challenges in developing fully human antibodies of a known human protein). It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). However, the record here does not indicate such an established correlation. Instead, AbbVie used a trial and error approach to modify individual amino acids in order to improve the IL-12 binding affinity. Moreover, the ’128 and ’485 patents do not describe any common structural features of the claimed antibodies. The asserted claims attempt to claim every fully human IL-12 antibody that would achieve a desired result, *i.e.*, high binding affinity and neutralizing activity, and cover an antibody as different as Stelara, whereas the patents do not describe representative examples to support the full scope of the claims.

We therefore conclude that substantial evidence supports the jury verdict of invalidity for lack of an adequate written description of the claimed genus and affirm the district court’s denial of JMOL on that issue. Consequently, we need not address AbbVie’s argument regarding enablement.

...
Chapter 4: Utility


Manual of Patent Examining Procedure § 2107
9th Ed., March 2014

§ 2107. Guidelines for Examination of Applications for
Compliance with the Utility Requirement

I. Introduction

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112(a), or pre-AIA 35 U.S.C. § 112, ¶ 1. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112, nor are they designed to obviate the examiner’s review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

II. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the “useful invention” (“utility”) requirement of 35 U.S.C. § 101 and 35 U.S.C. § 112(a) or pre-AIA 35 U.S.C. § 112, ¶ 1.

(A) Read the claims and the supporting written description.

(1) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(2) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).

(3) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if

(i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and

(ii) the utility is specific, substantial, and credible.

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and
the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(i) A claimed invention must have a specific and substantial utility. This requirement excludes “throw-away,” “insubstantial,” or “nonspecific” utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. § 101.

(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant’s assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under 35 U.S.C. § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. § 112(a) or pre-AIA 35 U.S.C. § 112, ¶ 1, on the basis that the disclosure fails to teach how to use the invention as claimed. The 35 U.S.C. § 112(a) or pre-AIA 35 U.S.C. § 112, ¶ 1, rejection imposed in conjunction with a 35 U.S.C. § 101 rejection should incorporate by reference the grounds of the corresponding 35 U.S.C. § 101 rejection.

(3) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under 35 U.S.C. § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under 35 U.S.C. § 112(a) or pre-AIA 35 U.S.C. § 112, ¶ 1, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The … rejections shift the burden of coming forward with evidence to the applicant to:

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

(C) Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or
U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(1) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(2) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing must contain the following elements:

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(3) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

(D) A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.
Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR § 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.


...
Chapter 5: Novelty & Loss of Right

One cannot patent that which is old. One can patent only that which is new. Indeed, the Supreme Court has made this precept a constitutional constraint on the Patent Act: “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.” *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

That’s the easy part.

The hard part? Defining, for Patent Act purposes, what’s “old” and what’s “new.” There are three key dimensions in play: (a) the measuring date(s) one can use to prove that a claimed invention is old, (b) the materials one can use to prove that a claimed invention is old, and (c) the person(s) whose activities one can use to prove that a claimed invention is old. A further complication: the 1952 Patent Act (and minor amendments thereto) gives one batch of settings for those three dimensions, and the 2011 America Invents Act gives a dramatically different batch of settings for some of those three dimensions. In other words, this is tough legal terrain for a lawyer new to patent law. So, recall what the tortoise taught the hare and stick to it, slow and steady.

And one last distinction, to set up the first case below—We may want to set different rigors of disclosure, for the claimed invention C, when we establish, on the one hand, how much written-description disclosure by oneself is required to entitle one to claim C in one’s own patent (under § 112), versus when we establish, on the other hand, how much prior-art disclosure from another forecloses one from claiming C in one’s patent (under § 102). Which of the two, if either, should be more demanding, and why?

*Mueller’s Patent Law*: 173-175, 188-197

**In re Hafner**

410 F.2d 1403 (CCPA 1969)

*Rich, Judge:*

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claims 1, 3, and 4 of application serial No. 384,782, filed July 23, 1964, entitled “New Aldehydes of the Fulvene Series and New Processes of Preparing the Same.” No claim has been allowed.

This case comes to us with the following somewhat involved but important background. On August 17, 1959, appellant filed two German applications, one relating to certain fulvene derivatives and the other to certain cyclopentadiene derivatives. By appellant’s admission, neither German application contained any disclosure of utility, such disclosure having been unnecessary in Germany. On August 1,
1960, within one year of the German filings, appellant filed a U.S. application (the “parent” of the instant application) combining the two German disclosures. A claim of priority was made and the necessary certified copies of the German applications were filed. Although the parent application alleged that the claimed compounds are useful as intermediates for preparing certain artificial resins and indicated a manner in which such resins can be prepared, all claims were finally rejected under 35 U.S.C. § 112 because of an alleged failure of the specification to disclose how those resins might be put to use.

On April 27, 1961, during the pendency of the parent application, one of appellant’s two German applications (hereinafter referred to as “Hafner”) was published. More than one year thereafter, on July 24, 1964, the instant continuation-in-part application was filed. It contains a reference to the parent application, and a claim for priority going back to the German application was made at the time of filing. The instant application contains an amplified disclosure of utility and “how to use,” the adequacy of which, under 35 U.S.C. § 101 and § 112 respectively, has not been questioned.

All the appealed claims stand rejected as being “fully met (35 USC § 102)” by both Hafner and an article published in May 1960 by one Arnold. Assuming that these two references are valid § 102 references and considering their respective dates and the filing dates of appellant’s two German and two U.S. applications, the instant application must be entitled to the parent application’s U.S. filing date to overcome Hafner and the convention filing date of the German applications to overcome Arnold.

Until his brief before this court, appellant conceded that

*** the claims are met by *** Hafner and *** Arnold *** if the present application is not entitled to rely upon the filing date of the parent application *** and through it to *** [Hafner].

Now, however, appellant urges that these references do not qualify as “enabling” disclosures [and thus are not proper prior art references] because they allegedly do not “teach the public ‘how to use’ the invention ***.” Appellant also maintains that

*** the Patent Office is at once inconsistent and unfair in holding that the Arnold disclosure and the Hafner disclosure *** “fully meet” the appealed claims, and that the disclosure in the parent application which is even better than that in the Hafner reference fails to support the claims on appeal.

In essence, appellant is contending that a double standard should not be applied in determining the adequacy of a disclosure to anticipate under § 102, on the one hand, and to support the patentability of a claim under § 112 on the other. He feels that a disclosure adequate for the one purpose is necessarily adequate for the other but, unhappily for him, this is not so. As we shall develop, a disclosure lacking a teaching of how to use a fully disclosed compound⁵ for a specific, substantial utility

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⁵ By ‘fully disclosed compound’ is meant a compound for which a process of making is also disclosed or is obvious.
or of how to use for such purpose a compound produced by a fully disclosed process
is, under the present state of the law, entirely adequate to anticipate a claim to either
the product or the process and, at the same time, entirely inadequate to support the
allowance of such a claim. This is so because of the requirements of law engrafted on
sections 101 and 112 by the decision of the Supreme Court in Brenner v. Manson,
383 U.S. 519 (1966), with respect to the meaning to be given to the words “use-
ful” and “use” in those sections. In construing them, we must of course, give them
the meaning demanded by the Supreme Court.7

Standing alone, appellant’s argument against a double standard is a plausible
proposition. However, when considered in light of the specific provisions of § 102,
and § 112 as it has been interpreted, it is seen to be untenable—§ 112 provides that
the specification must enable one skilled in the art to “use” the invention whereas
§ 102 makes no such requirement as to an anticipatory disclosure. The disclosure of
how to use must relate to a use of the kind considered by the Supreme Court in
Brenner v. Manson to be a sufficient utility. The majority of this court has spoken in
Kirk and Joly as to its construction of the Manson requirement. Thus, the double
standard which appellant criticizes is now, implicitly if not explicitly, required by
law, at least in situations such as we have here, although the “invention” per se
claimed is fully disclosed and though the manner of “making,” as distinguished from
“using,” the invention is also fully disclosed or is obvious.

Returning now to the question of appellant’s right to his claims of priority, the
examiner held appellant not entitled to the filing date of either his German applica-
tions or his parent U. S. application because the latter allegedly did not comply with
§ 112 (as required by § 120) in that the “how to use” requirement of § 112 was not
met.

The only “how to use” disclosure in the parent application reads:

The new products are valuable intermediate products especially for prepar-
ing artificial resins and plastic masses such as unsaturated linear or cross-
linked long-chained acetal resins or mixed acetal-polyester resins which
may be copolymerized with monomeric vinyl compounds such as styrene
or diallylphthalate.

The examiner and board were of the view that, although persons skilled in the
art might well have no difficulty preparing acetal resins from the compounds of app-
ellant’s invention, the parent application disclosure was still inadequate under
§ 112 because there is no express disclosure of a specific use to which the resulting
resins can be put, and appellant has not shown that such a use would be obvious.

7 The writer of the present opinion on behalf of the court writes, of course, on the
basis of the law as it is, notwithstanding his personal views that it should be other-
wise for reasons fully expressed in In re Nelson, 280 F.2d 172 (CCPA 1960), and in
his dissenting opinion in In re Kirk, 376 F.2d 936 (CCPA 1967), augmented by
the late Judge Smith’s dissenting opinion in the companion case of In re Joly, 376
F.2d 906 (CCPA 1967).
After carefully reviewing the record and appellant’s arguments and in view of the law as established by Brenner v. Manson, Kirk, and Joly, the decision below appears to be correct.\(^8\)

While arguing that his parent application did in fact comply with the first paragraph of § 112, appellant also maintains that § 120\(^9\) only requires that a “previously filed” U.S. application disclose the “invention” as required by § 112 and does not require that it also disclose “the manner and process of making and using it.” Appellant correctly points out that the utility of an invention is distinct from “the invention” \textit{per se} and from this argues that only “the invention” need be disclosed. If § 120 spoke only of an “invention disclosed in an application previously filed in the United States,” which it does not, appellant’s interpretation might well be unassailable.\(^11\) This section, however, also makes specific reference to the first paragraph of § 112. From this we think it clear that § 120 means that, to be entitled to the benefits provided by that section, the invention disclosed in the “previously filed” application must be described therein in such a manner as to satisfy all the requirements of the first paragraph of § 112 as the courts have construed it, including that which requires the description to be sufficient to enable one skilled in the art to use the same for a legally adequate utility. We therefore find appellant not entitled to the benefit of the parent filing date.

Finally, appellant argues that the instant application is entitled to the filing date of the German applications even though we find it is not entitled to the date of the parent U.S. application. We have carefully considered appellant’s extensive argu-

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\(^8\) But for these decisions and their stringent requirements as to the kind of ‘utility’ which must be disclosed in compliance with the ‘how to use’ requirement of the first paragraph of § 112, the writer personally would agree with appellant herein that the disclosure of how to use in his parent application, quoted above, complies with the statutory requirements, which would entitle the present continuation-in-part application to the parent’s filing date. But the writer’s personal views are not the law.

\(^9\) “Benefit of earlier filing date in the United States—An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application ***.”

\(^11\) Compare the wording of 35 U.S.C. § 119. [ \textit{Ed. Note: At the time, § 119 provided that “[a]n application for patent for an invention filed in this country by any person who has … previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States … shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed ….” This portion is now in § 119(a), and the textual difference from § 120 remains. ]
ments but hold that the express language of §§ 119 and 120 requires the contrary conclusion for the reasons stated above. Appellant has argued that his failure to disclose adequately the utility of his invention is a mere “technical” defect which he could have cured by an amendment of his parent U.S. application (35 U.S.C. § 132), instead of by the continuation-in-part application which he chose. We have to disagree. As we said in … In re Nelson,

Of course, if the application had been fatally defective *** such a defect could not have been cured by an amendment the object of which was to put into the specification something required to be there when it was filed.

Here the parent application is found to be fatally defective. … What was added in the continuation-in-part to render it adequate under the law was clearly “new matter” under 35 U.S.C. § 132.

Because of the primary ground of our decision— inability to obtain the benefit of the filing date of the U. S. parent application—it follows that appellant does not get the benefit of the filing date of the German applications on which it was based.

The decision of the board is affirmed.

**Inherent Anticipation**

Mueller’s Patent Law 175-188

In re Cruciferous Sprout Litigation

301 F.3d 1343 (Fed. Cir. 2002)

Prost, Judge:

Brassica Protection Products LLC and Johns Hopkins University (collectively “Brassica”) appeal from the decision … granting summary judgment that U.S. Patent Nos. 5,725,895; 5,968,567; and 5,968,505 are invalid as anticipated by the prior art. We affirm the district court’s ruling.

Background

The three patents-in-suit relate to growing and eating sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Specifically, the patents describe methods of preparing food products that contain high levels of substances that induce Phase 2 enzymes. These enzymes are part of the human body’s mechanism for detoxifying potential carcinogens. Thus, they have a chemoprotective effect against cancer. Foods that are rich in glucosinolates, such as certain cruciferous sprouts, have high Phase 2 enzyme-inducing potential. The inventors of the patents-in-suit recognized that the Phase 2 enzyme-inducing agents (or their glucosinolate precursors) are far more concentrated in certain sprouts (such as broccoli and cauliflower but not cabbage, cress, mustard or radish) that are harvested before the two-leaf stage than in corresponding adult plants. However, glucosinolate levels in cruciferous plants can be highly variable. According to the inventors, it is therefore desirable to select the seeds of those cruciferous plants which, when germinated and harvested before the two-leaf stage, produce sprouts that contain high levels of the desired enzyme-inducing potential.
The ’895 patent was filed on September 15, 1995, and claims, inter alia, “A method of preparing a food product rich in glucosinolates, comprising germinating cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.” ’895 patent, claim 1. The ’567 patent is a continuation of the ’895 application and it claims a “method of preparing a human food product” from sprouts. ’567 patent, claims 1 and 9. The ’505 patent is a divisional of the ’895 application and it claims a “method of increasing the chemoprotective amount of Phase 2 enzymes in a mammal,” as well as a “method of reducing the level of carcinogens in a mammal,” by creating a “food product” from sprouts and then “administering said food product” to a mammal. ’505 patent, claims 1 and 16.

The three patents-in-suit are owned by Johns Hopkins University and exclusively licensed to Brassica Protection Products LLC. Johns Hopkins and Brassica sued Sunrise Farms, Becky Crikelair, Frank Crikelair, Edrich Farms, Inc., Edward B. Stanfield, III, Edward F. Stanfield, Jr., Richard Stanfield, Sally F. Stanfield, Banner Mountain Sprouts, Banner Mountain Sprouts, Inc., Lawrence Ravitz, Harmony Farms, International Specialty Supply, Greg Lynn, Lorna Lynn and Robert L. Rust in various district courts. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation consolidated the various cases in the District of Maryland for pretrial proceedings. On June 7, 2001, the defendants filed a joint motion for partial summary judgment of invalidity, arguing that the patents were anticipated by prior art references disclosing growing and eating sprouts. Brassica filed a cross-motion for summary judgment that the patents are not invalid. ...

On August 10, 2001, the court granted defendants’ motion for summary judgment of invalidity and denied Brassica’s cross-motion for summary judgment. According to the district court, “[t]he record before the Court makes it abundantly clear that, prior to the issuance of the patents-in-suit, one skilled in the art could, by following the teachings of the prior art, germinate broccoli seeds, harvest the sprouts, and sell them as a food product.” While recognizing that the inventors of the patents-in-suit may have discovered a new and significant property of certain types of cruciferous sprouts, the district court concluded that “merely describing unexpected beneficial results of a known process does not entitle Plaintiffs to patent that process.” Thus, a “plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature.” …

Discussion

... Anticipation is a question of fact, Gen. Elec. Co. v. Nintendo Co., 179 F.3d 1350, 1353 (Fed. Cir. 1999), and is determined by first construing the claims and then comparing the properly construed claims to the prior art, Gechter v. Davidson, 116 F.3d 1454, 1457 (Fed. Cir. 1997). ...

I.

Brassica contends that the district court erroneously construed the claims by failing to treat the preamble of claim 1 of the ’895 patent as a limitation of the claims. In addition, Brassica argues that the district court failed to construe the limi-
tations “rich in glucosinolates” (appearing in claims 1 and 9 of the ’895 patent) and “high Phase 2 enzyme-inducing potential” (appearing in claim 1 of the ’567 patent and claims 1 and 16 of the ’505 patent).

No litmus test defines when a preamble limits claim scope. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). Whether to treat a preamble as a limitation is a determination “resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” Id.; Catalina Mktg. Int’l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). In general, a preamble limits the claimed invention if it recites essential structure or steps, or if it is “necessary to give life, meaning, and vitality” to the claim. Catalina Mktg., 289 F.3d at 808. Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention. Catalina Mktg., 289 F.3d at 808.

In this case, both the specification and prosecution history indicate that the phrase “rich in glucosinolates” helps to define the claimed invention and is, therefore, a limitation of claim 1 of the ’895 patent. The specification, for example, states that “this invention relates to the production and consumption of foods which are rich in cancer chemoprotective compounds.” ’895 patent, col. 1, ll. 18-19. A stated object of the invention is “to provide food products and food additives that are rich in cancer chemoprotective compounds.” Id. at col. 2, ll. 38-39. The specification therefore indicates that the inventors believed their invention to be making food products that are rich in chemoprotective compounds, or, in other words, food products “rich in glucosinolates.”\(^1\) In addition, during reexamination of the ’895 patent the patentee argued as follows:

Claim 1 of the patent, for example, is directed to “[a] method of preparing a food product rich in glucosinolates, *** and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.” *** Although “rich in glucosinolates” is recited in the preamble of the claim, the pertinent case law holds that the preamble is given weight if it breathes life and meaning into the claim. *** Accordingly, the cited prior art does not anticipate the claims because it does not explicitly teach a method of preparing a food product comprising cruciferous sprouts that are rich in glucosinolates or contain high levels of Phase 2 inducer activity.

This language shows a clear reliance by the patentee on the preamble to persuade the Patent Office that the claimed invention is not anticipated by the prior art. As such, the preamble is a limitation of the claims.

\(^1\) Phase 2 enzymes are part of the human body’s mechanism for detoxifying potential carcinogens. These enzymes therefore have a chemoprotective effect against cancer. According to the ’895 patent, “most of the [Phase 2 enzyme] inducer potential of crucifer plants is due to their content of isothiocyanates and their biogenic precursors, glucosinolates.” ’895 patent, col. 8, ll. 14-16.
Brassica also asks this court to construe the phrases “rich in glucosinolates” and “high Phase 2 enzyme-inducing potential” to require “at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential at 3-days following incubation under conditions in which cruciferous seeds germinate and grow.” ’895 patent, col. 7, ll. 47-53.

“[T]he words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor.” *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1577 (Fed. Cir. 1993). However, “limitations appearing in the specification will not be read into claims, and interpreting what is meant by a word in a claim ‘is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.’” *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989). Brassica’s proposed construction violates this rule by improperly importing limitations from the specification into the claims. True, the specification states that “[s]uitable sprouts will have at least 200,000 units per gram of fresh weight of Phase 2 enzyme-inducing potential following 3-days incubation of seeds under conditions in which the seeds germinate and grow.” ’895 patent, col. 10, l. 66 – col. 11, l. 2. The specification does not, however, indicate that the phrases “rich in glucosinolates” or “high in Phase 2 enzyme-inducing potential” are limited to these precise conditions. Rather, the specification uses the term “high” in its ordinary, comparative sense to mean “not low.”... Likewise, the term “rich” is not specifically defined or limited by the specification, but instead is used in its ordinary, relative sense.

Brassica’s proposed construction is also inconsistent with the language of the dependent claims. Claim 19 of the ’567 patent recites: “The method according to claim 1, wherein said seeds produce cruciferous sprouts containing at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential measured after 3-days of growth.” Brassica’s proposed construction would render this claim meaningless. See *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (finding a violation of the doctrine of claim differentiation when a proposed construction would render another claim superfluous). We therefore reject Brassica’s proposed claim construction for the phrases “rich in glucosinolates” and “high in Phase 2 enzyme-inducing potential.”

**II.**

Having construed the claim limitations at issue, we now compare the claims to the prior art to determine if the prior art anticipates those claims. In order to prove that a claim is anticipated under 35 U.S.C. § 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992).

Brassica argues that the prior art does not expressly or inherently disclose the claim limitations of “preparing a food product rich in glucosinolates” (claims 1 and 9 of the ’895 patent), or “identifying seeds which produce cruciferous sprouts containing high Phase 2 enzyme-inducing potential” (claims 1 and 16 of the ’505 patent, claim 1 of the ’567 patent). According to Brassica, the prior art merely dis-
discusses growing and eating sprouts without mention of any glucosinolates or Phase 2 enzyme-inducing potential, and without specifying that particular sprouts having these beneficial characteristics should be assembled into a “food product.” Moreover, Brassica argues, the prior art does not inherently disclose these limitations because “at most, one following the prior art would have a possibility or probability of producing a food product high in Phase 2 enzyme-inducing potential” and the “fact that one following the prior art might have selected seeds meeting the limitations of the claims is not sufficient to establish inherent anticipation.”

It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. See, e.g., Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342 (Fed. Cir. 1999); Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” MEHL/Biophile Int’l Corp. v. Milgram, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (finding anticipation of a method of hair depilation by an article teaching a method of skin treatment but recognizing the disruption of hair follicles, citing In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986)). “Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” MEHL/Biophile, 192 F.3d at 1365; Atlas Powder, 190 F.3d at 1347.

Brassica does not claim to have invented a new kind of sprout, or a new way of growing or harvesting sprouts. Rather, Brassica recognized that some sprouts are rich in glucosinolates and high in Phase 2 enzyme-inducing activity while other sprouts are not. See ’895 patent, col. 10, ll. 28-42 (“Sprouts suitable as sources of cancer chemoprotectants are generally cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts.”). But the glucosinolate content and Phase 2 enzyme-inducing potential of sprouts necessarily have existed as long as sprouts themselves, which is certainly more than one year before the date of application at issue here. See, e.g., Karen Cross Whyte, The Complete Sprouting Cookbook 4 (1973) (noting that in “2939 B.C., the Emperor of China recorded the use of health giving sprouts”). Stated differently, a sprout’s glucosinolate content and Phase 2 enzyme-inducing potential are inherent characteristics of the sprout. Cf. Brian R. Clement, Hippocrates Health Program 8 (1989) (referring to “[i]nherent enzyme inhibitors, phytates (natural insecticides), oxalates, etc., present in every seed”). It matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics of the sprouts. MEHL/Biophile, 192 F.3d at 1365.

Titanium Metals Corp. v. Banner is particularly instructive in this regard. In that case, the claim at issue recited:

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3 “A food product is any ingestible preparation containing the sprouts of the instant invention, or extracts or preparations made from these sprouts ***.” ’895 patent, col. 6, ll. 26-28.
A titanium base alloy consisting essentially by weight of about 0.6% to 0.9% nickel, 0.2% to 0.4% molybdenum, up to 0.2% maximum iron, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments.

Titanium Metals, 778 F.2d at 776. The prior art disclosed a titanium base alloy having the recited components of the claim, but the prior art did not disclose that such an alloy was “characterized by good corrosion resistance in hot brine environments.” We nevertheless held that the claim was anticipated by the prior art, because “it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties.” Id. at 782. Titanium Metals explained the rationale behind this common sense conclusion:

The basic provision of Title 35 applicable here is § 101, providing in relevant part: “Whoever invents or discovers any new *** composition of matter, or any new *** improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

***

*** [C]ounsel never came to grips with the real issues: (1) what do the claims cover and (2) is what they cover new? Under the laws Congress wrote, they must be considered. Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties.

Id. at 780, 782. Brassica has done nothing more than recognize properties inherent in certain prior art sprouts, just like the corrosion resistance properties inherent to the prior art alloy in Titanium Metals.4 While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new.

Brassica nevertheless argues that its claims are not anticipated because the prior art does not disclose selecting the particular seeds that will germinate as sprouts rich in glucosinolates and high in Phase 2 enzyme-inducing potential (as opposed to selecting other kinds of seeds to sprout) in order to form a food product. We disagree. The prior art teaches sprouting and harvesting the very same seeds that the patents recognize as producing sprouts rich in glucosinolates and having high Phase 2 enzyme-inducing potential. According to the patents, examples of suitable sprouts are typically from the family Cruciferea, of the tribe Brassiceae, and of the sub-tribe Brassicinae. Preferably the sprouts are Brassica oleracea selected from the group of varieties consisting of acephala (kale, collards, wild cabbage,

4 Most of the claims at issue are method claims, not composition or product claims. Nevertheless, the principles of Titanium Metals still apply. See, e.g., MEHL/Biophile, 192 F.3d at 1366–67 (finding anticipation by inherency of a method of hair depilation); Bristol–Myers, 246 F.3d at 1376 (Fed. Cir. 2001) (stating that “[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent”).
curly kale), medullosa (marrowstem kale), ramosa (thousand head kale), alboglobabra (Chinese kale), botrytis (cauliflower, sprouting broccoli), cos-tata (Portugese kale), gemmifera (Brussels sprouts), gongylodes (kohlrabi), italica (broccoli), palmifolia (Jersey kale), sabauda (savoy cabbage), sabelli-ca (collards), and selensia (borecole), among others.

'895 patent, col. 10, ll. 32-42. Numerous prior art references identify these same sprouts as suitable for eating. See, e.g., Stephen Facciola, Cornucopia: A Source Book of Edible Plants 47 (1990) (listing “Brassica oleracea Botrytis Group Cauliflower … Sprouted seeds are eaten”), Esther Munroe, Sprouts to Grow and Eat 9-14 (1974) (identifying “Broccoli, Brussels sprouts, Cabbage, Cauliflower, Collards and Kale”). These references therefore meet the claim limitation of identifying seeds to use in order to have sprouts with the inherent properties of glucosinolates and high Phase 2 enzyme-inducing activity. Despite the patents’ admissions about the suitability of particular plant species found in these prior art references, Brassica argues that only specific cultivars of these plant species are rich in glucosinolates and high in Phase 2 enzyme-inducing activity. Thus, according to Brassica, the prior art fails to meet the “identifying” steps of the claims because it does not specify which cultivars should be sprouted. However, all of the appropriate cultivars that are identified in Brassica’s patent are in the public domain. '895 patent, col. 10, ll. 43-65. Brassica cannot credibly maintain that no one has heretofore grown and eaten one of the many suitable cultivars identified by its patents. It is unnecessary for purposes of anticipation for the persons sprouting these particular cultivars to have realized that they were sprouting something rich in glucosinolates and high in Phase 2 enzyme-inducing potential. Atlas Powder, 190 F.3d at 1348 (“The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup of the underlying scientific principles which allow them to operate.”).

The prior art also discloses the remaining limitations of the claims. The Munroe reference, for example, recommends that sprouts be harvested between “3 to 5 days for a sprouted length of ½ to 1 inch.” Munroe at 9. Photographs of these sprouts show that they have not yet reached the two-leaf stage of development. Id. at 10-13. Thus, this reference discloses the claim limitations of germinating the appropriate cruciferous seeds and harvesting the resulting sprouts prior to the 2-leaf stage. See '895 patent, claims 1 and 9; '567 patent, claims 1 and 2; '505 patent, claims 1 and 16. Munroe also discloses that these particular sprouts can be used in food products such as “soups, salads and main dishes,” id. at p. 14, thereby meeting the claim limitation of forming a food product comprising a plurality of the sprouts ('895 patent claims 1 and 9; '567 patent, claims 1 and 8; '505 patent, claims 1 and 16) and the claim limitation of administering (eating) the food product ('505 patent, claims 1 and 16). The Munroe reference therefore discloses each and every limitation of these claims of the patents.

In summary, the prior art inherently contains the claim limitations that Brassica relies upon to distinguish its claims from the prior art. While Brassica may have recognized something about sprouts that was not known before, Brassica’s claims do not describe a new method.
Conclusion

For the foregoing reasons, we affirm the district court’s summary judgment that the claims at issue are anticipated by the prior art. The prior art indisputably includes growing, harvesting and eating particular sprouts which Brassica has recognized as being rich in glucosinolates and high in Phase 2 enzyme-inducing potential. But the glucosinolate content and Phase 2 enzyme-inducing potential of these sprouts are inherent properties of the sprouts put there by nature, not by Brassica. Brassica simply has not claimed anything that is new and its claims are therefore invalid.

**Schering Corp. v. Geneva Pharmaceuticals, Inc.**

339 F.3d 1373 (Fed. Cir. 2003)

_Rader, Judge:_

On summary judgment, the United States District Court for the District of New Jersey determined that claims 1 and 3 of U.S. Patent No. 4,659,716 are invalid. Because the district court correctly found that U.S. Patent No. 4,282,233 inherently anticipates claims 1 and 3 of the ’716 patent, this court affirms.

I.

Schering Corporation (Schering) owns the ’233 and ’716 patents on antihistamines. Antihistamines inhibit the histamines that cause allergic symptoms.

The prior art ’233 patent covers the antihistamine loratadine, the active component of a pharmaceutical that Schering markets as CLARITIN. Unlike conventional antihistamines when CLARITIN was launched, loratadine does not cause drowsiness.

The more recent ’716 patent at issue in this case covers a metabolite of loratadine called descarboethoxyloratadine (DCL). A metabolite is the compound formed in the patient’s body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound. The metabolite DCL is also a non-drowsy antihistamine. The ’716 patent issued in April 1987 and will expire in April 2004 (the ’233 patent issued in 1981 and has since expired).

... The ’233 patent issued on August 4, 1981, over one year before the earliest priority date of the ’716 patent, February 15, 1984. The ’233 patent is thus prior art to the ’716 patent. See 35 U.S.C. § 102(b). The ’233 patent discloses a class of compounds including loratadine (disclosed in Example 1B). The ’233 patent claims loratadine in claim 7. The ’233 patent claims four other compounds in claims 8-11. Examples 6-7 are prophetic examples of pharmaceutical compositions (a syrup and a tablet), each containing an unidentified “active compound.” The ’233 patent does not expressly disclose DCL and does not refer to metabolites of loratadine.

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1 Prophetic examples are set forth in the present tense to indicate that they were not carried out. _Atlas Powder Co. v. E.I. du Pont De Nemours & Co._, 750 F.2d 1569, 1578 (Fed. Cir. 1984).
The numerous defendants-appellees sought to market generic versions of loratadine once the ’233 patent expired. Seeking regulatory approval, each appellee submitted an application to the Food and Drug Administration (FDA). Because Schering included the ’716 patent in the Orange Book listing for loratadine, the applications also contained a certification that the ’716 patent was invalid. The appellees notified Schering of the FDA filings.

After receiving notice of the FDA filings, Schering filed suit for infringement. See 35 U.S.C. § 271(e)(2)(A). After discovery, the parties filed cross motions for summary judgment on the validity issue. The district court construed claims 1 and 3 of the ’716 patent to cover DCL in all its forms, including “metabolized within the human body” and “synthetically produced in a purified and isolated form.” The parties agreed to that construction. Applying that claim construction, the district court found that the ’233 patent did not expressly disclose DCL. Nonetheless, the district court also found that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the ’233 patent. The district court concluded that the ’233 patent anticipated claims 1 and 3 of the ’716 patent under 35 U.S.C. § 102(b). The district court therefore granted the appellees’ motions for summary judgment of invalidity. …

II.

A.

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art. … [P]recedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. E.g., In re Cruciferous Sprout Litig., 301 F.3d 1343, 1351 (Fed. Cir. 2002); MEHL/Biophile Int’l Corp. v. Milagraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (“Where *** the result is a necessary consequence of what was deliberately intended, it is of no import that the article’s authors did not appreciate the results.”); Atlas Powder, 190 F.3d at 1348-49 (“Because ‘sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. *** An inherent structure, composition, or function is not necessarily known.”). Thus, recognition by a person of ordinary skill in the art before the critical date of the ’716 patent is not required to show anticipation by inherency. The district court therefore did not err in allowing for later recognition of the inherent characteristics of the prior art ’233 patent.

Cases dealing with “accidental, unwitting, and unappreciated” anticipation … do not show that inherency requires recognition. See Eibel Process Co. v. Minn. &

In contrast to the present case, the record in Eibel and Tilghman did not show that the prior art produced the claimed subject matter. The patent at issue in Tilghman claimed a method of forming free fatty acids and glycerine by heating fats with water at high pressure. In Tilghman, the record did not show conclusively that the claimed process occurred in the prior art. In reviewing the prior art, the Court referred hypothetically to possible disclosure of the claimed process. For example, the Court stated “[w]e do not regard the accidental formation of fat acid in Perkins’s steam cylinder *** (if the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence in this inquiry.” Tilghman, 102 U.S. at 711. In Eibel, the Court found no evidence of the claimed subject matter in the prior art.

Applying an inherency principle in the context of an on sale bar under 35 U.S.C. § 102(b), this court has distinguished Eibel and Tilghman. See Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315, 1319 (Fed. Cir. 1999) (“If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.”); Scaltech, Inc. v. Retec/Tetra, LLC, 269 F.3d 1321, 1330 (Fed. Cir. 2001) (“[A]ppreciation of the invention is not a requirement to trigger the statutory [on sale] bar.”). In those cases, the product sold or offered for sale had an inherent, but unrecognized, feature that was a limitation of the asserted claims. …

… DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients. The record also shows that DCL provides a useful result, because it serves as an active non-drowsy antihistamine. In sum, this court’s precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.

B.

This court recognizes that this may be a case of first impression, because the prior art supplies no express description of any part of the claimed subject matter. The prior art ’233 patent does not disclose any compound that is identifiable as DCL. In this court’s prior inherency cases, a single prior art reference generally contained … a partial description missing certain aspects. Inherency supplied the missing aspect of the description. Upon proof that the missing description is inherent in the prior art, that single prior art reference placed the claimed subject matter in the public domain. This case does not present the issue of a missing feature of the claimed invention. Rather, the new structure in this case, DCL, is not described by the prior ’233 patent.

…
Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the “natural result flowing from” the explicit disclosure of the prior art. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001); see also In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound’s existence was not known).

In reaching this conclusion, this court is aware of In re Seaborg, 328 F.2d 996 (CCPA 1964). In that case, this court’s predecessor considered claims drawn to an isotope of americium made by nuclear reaction in light of a prior art patent disclosing a similar nuclear reaction process but with no disclosure of the claimed isotope. The court reversed a [PTO] rejection of the claims for lack of novelty. This court’s predecessor found that the prior art process did not anticipate the claims because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material, i.e., the isotope would have been undetectable. Id. at 998-99 (“[T]he claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable.”). In this case, DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratadine.

This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter. The patent law principle “that which would literally infringe if later in time anticipates if earlier,” Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001), bolsters this conclusion. Similarly, “if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated.” Atlas Powder, 190 F.3d at 1346. “The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.” Id. at 1348. Thus, inherency operates to anticipate entire inventions as well as single limitations within an invention.

Turning to this case, the use of loratadine would infringe claims 1 and 3 of the ’716 patent covering the metabolite DCL. This court has recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite. See Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997) (“[T]he right to exclude may arise from the fact that when administered, [the accused product] metabolizes into another product *** which Hoechst has claimed.”); see also Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1421-22 (Fed. Cir. 1994) (stating that a compound claim could cover a compound formed upon ingestion). An identical metabolite must then anticipate if earlier in time than the claimed compound.
The record shows that the metabolite of the prior art loratadine is the same compound as the claimed invention. Claims 1 and 3 are compound claims . . . DCL is within the scope of claims 1 and 3. Because the prior art metabolite inherently disclosed DCL, claims 1 and 3 are anticipated and invalid. In other words, the record shows that a patient ingesting loratadine would necessarily metabolize that compound to DCL. That later act would thus infringe claims 1 and 3. Thus, a prior art reference showing administration of loratadine to a patient anticipates claims 1 and 3.

C. This court next examines whether Schering’s secret tests of loratadine before the critical date placed DCL in the public domain. Before the critical date, Schering only tested loratadine in secret. Thus, according to Schering, “DCL was not publicly used, or described in any printed publication, until after February 15, 1983, the critical date for the ’716 patent under 35 U.S.C. § 102(b).” Schering thus argues that DCL did not “exist” in the public domain such that DCL could be prior art against the ’716 patent.

Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure. In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Thus, actual administration of loratadine to patients before the critical date of the ’716 patent is irrelevant. The ’233 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the administration of loratadine to patients.

Thus, this court examines whether the ’233 patent contains an enabling disclosure of DCL. A reference may enable one of skill in the art to make and use a compound even if the author or inventor did not actually make or reduce to practice that subject matter. Bristol-Myers, 246 F.3d at 1379; see also In re Donohue, 766 F.2d at 533 (sustaining an anticipation rejection over a reference disclosing a compound and other references disclosing sufficient information to make that compound). Indeed, information arising after the critical date may show that the claimed subject matter, as disclosed in a prior art reference, “was in the public’s possession.” Bristol-Myers, 246 F.3d at 1379 (citing In re Donohue, 766 F.2d at 534).

An anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more. To qualify as an enabled reference, the ’233 patent need not describe how to make DCL in its isolated form. The ’233 patent need only describe how to make DCL in any form encompassed by a compound claim covering DCL, e.g., DCL as a metabolite in a patient’s body. The ’233 patent discloses administering loratadine to a patient. A person of ordinary skill in the art could practice the ’233 patent without undue experimentation. The inherent result of administering loratadine to a patient is the formation of DCL. The ’233 patent thus provides an enabling disclosure for making DCL.

D.

Finally, this court’s conclusion on inherent anticipation in this case does not preclude patent protection for metabolites of known drugs. With proper claiming, patent protection is available for metabolites of known drugs. Cf. In re Kratz, 592
F.2d 1169, 1174 (CCPA 1979) (stating that a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound); In re Bergstrom, 427 F.2d 1394, 1401-02 (CCPA 1970) (stating that a material occurring in nature in less pure form does not anticipate claims to the pure material).

But those metabolites may not receive protection via compound claims. In this case, for instance, claims 1 and 3 broadly encompass compounds defined by structure only. Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug. As this case holds, these broad compound claims are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound.

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in Kratz and Bergstrom, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition. The ’233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the ’233 patent does not disclose isolation of DCL.

The ’716 patent contains claims 5-13 covering pharmaceutical compositions and claims 14-16 covering methods of treating allergic reactions by administering compounds that include DCL. These claims were not found anticipated by the ’233 patent.

III.

The district court found that “there is no genuine issue that the consumption of loratadine by humans, with a wide variety of health statuses, necessarily results in the natural production in the human body of the DCL metabolite.” This court must also examine the record for any genuine issue of material fact about whether ingestion of loratadine necessarily produces DCL. The record does, for instance, contain expert testimony, including a proposed metabolic scheme and animal data, that questions whether ingestion of loratadine always forms DCL.

... In this case, the evidence supporting the district court’s conclusion is extensive. In thirteen clinical studies that Schering ran before May 1, 1987, all 144 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. The district court found “no reports in any of the studies of any individual who did not metabolically produce DCL following the administration of loratadine.” The appellees reported twenty-one clinical studies in which loratadine was administered to a total of 864 patients, all of whom formed measurable amounts of DCL in their systems. In addition, the record shows that since 1985 Schering’s technical articles and [SEC] filings referred to DCL as the metabolite of loratadine. Also the Food and Drug Administration, the corresponding European agency, the Physician’s Desk Reference, and Schering’s CLARITIN package insert referred to DCL as the major metabolite of loratadine.
The record presents no data on humans to show that a genuine factual dispute exists about the formation of DCL after ingesting loratadine. Indeed Schering’s own expert testified that no human has been found that does not metabolize loratadine to DCL, and that “[t]here is no scientific data in the published literature that says that DCL is not formed from loratadine in humans.” Based on this record, no reasonable jury could find that DCL is not produced when a human ingests loratadine. This court therefore discerns no genuine issue of material fact.

... 

In re Ngai

367 F.3d 1336 (Fed. Cir. 2004)

Per Curiam

Petitioners John Ngai and David Lin (collectively “Ngai”) appeal from the decision by the Board of Patent Appeals and Interferences (“Board”) rejecting claim 19 of the petitioner’s patent application No. 09/597,608 as being anticipated by prior art. We find that the Board’s decision is supported by substantial evidence and accordingly affirm.

I. Background

The study of nucleic acids, including ribonucleic acids (“RNA”), has a wide variety of applications in the field of biological sciences. Unfortunately, oftentimes the amount of RNA that experimenters can extract from the cells can be quite small. Experimenters must duplicate the material many times over to assemble a quantity sufficient for experimentation. This process is called “amplification.” Additionally, some RNA strands may be difficult to detect in cells. A process called “normalization” enhances experimenters’ ability to detect the RNA that is expressed at low levels.

Ngai invented a new method for amplifying and normalizing RNA. He submitted the ’608 application to patent this invention. The ’608 application contained [19 relevant] claims. Claims 1-18 are drawn to a method of amplifying RNA. ...

Claim 19 is drawn to a kit designed to perform the method recited in Claim 1. Claim 19 reads:

A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

(Emphasis added).

Ngai does not dispute that prior art teaches a kit comprising instructions and a 10X buffer.¹

¹ Ngai also does not dispute that a 10X buffer is a type of buffer mentioned in proposed claim 19.
The Examiner allowed claims 1-18 but rejected claim[ ] 19 … under 35 U.S.C. § 102(b) … .

The Board agreed with the Examiner that prior art anticipates claim 19 because it teaches each and every limitation of the claim including instructions and a buffer agent. The Board concluded that the only difference between the prior art and claim 19 is the content of the instructions. Finding that the content of the instructions was not “functionally related” to the kit, the Board concluded that claim 19 should be rejected as anticipated by prior art.

Ngai appealed the Board’s decision to this Court. The only issue presented by this appeal is whether claim 19 should have been allowed. …

II. Standard of Review

Anticipation is a question of fact. In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We review PTO’s factual findings for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

III. Discussion

Ngai argues that the addition of new printed matter to a known product makes the product patentable. He rests his argument on the fact that claim 19 is limited to kits containing instructions teaching the method described in claim 1. Ngai argues that because prior art does not teach a limitation of “instructions describing the method of claim 1,” combined with an amplification kit, the petitioner’s claim cannot be anticipated. Ngai relies on the language of In re Gulack, 703 F.2d 1381 (Fed. Cir. 1983): “[T]he difference between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter.” Id. at 1385.[*]

The PTO argues that Ngai’s claim merely teaches a new use for an existing product. Thus, according to the PTO, Ngai can claim the new use as a method, but he cannot claim the existing product itself. The PTO relies on a different passage of Gulack and argues that in order to qualify under Gulack, the printed matter[†] must be functionally related to the underlying object. “The critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.” Id. at 1386.

The dispute between Ngai and PTO reduces to the question of the proper meaning of Gulack. The PTO has the better argument. In Gulack, the Board rejected a claim directed to a circular band designed for mathematical and educational purposes. The invention consisted of “(1) a band, ring, or set of concentric rings; [*] [Ed. Note — The application on appeal in Gulack ultimately issued as U.S. Patent No. 4,416,633. ]

[†] [Ed. Note — As Mueller’s Patent Law explains, at 384 n.202, “[t]he printed matter rejection originated with pre-1952 Act decisions of the CCPA, which declared that ‘the mere arrangement of printed matter on a sheet or sheets of paper does not constitute patentable subject matter’ In re Sterling, 720 F.2d 910, 912 (CCPA 1983).” ]
(2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed.” *Id.* at 1387. The rejection was premised upon the fact that a circular band with items printed upon it was well known in the art. See *id.* at 1384. We reversed, finding that the numbers printed on the band had a functional relationship to the band itself. The Court stated: “[t]he[] digits are related to the band in two ways: (1) the band supports the digits; and (2) there is an endless sequence of digits—each digit residing in a unique position with respect to every other digit in an endless loop. Thus, the digits exploit the endless nature of the band.” *Id.* at 1386-87. Although the prior art disclosed a band with printed matter, the Court concluded that the prior art neither “disclose[d] nor suggest[ed] either feature” of Gulack’s invention. *Id.* at 1387.

This case, however, is dissimilar from *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for “educational and recreational mathematical” purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the *Gulack* court pointed out, “[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” *Id.* If we were to adopt Ngai’s position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by *Gulack*. Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.

... King Pharmaceuticals, Inc. v. Eon Labs, Inc.

616 F.3d 1267 (Fed. Cir. 2010)

Gajarsa, Judge:

King Pharmaceuticals ... appeal[s] the ... grant of Eon Labs, Inc.’s motion for summary judgment that all claims of U.S. Patent Nos. 6,407,128 and 6,683,102 are invalid. In granting Eon’s motion, the district court held ... [some of the claims] invalid under 35 U.S.C. § 102.

... For the reasons stated below, we affirm the district court’s grant of summary judgment of invalidity. ...

Background

King markets and sells a name brand version of metaxalone called Skelaxin. Metaxalone is a muscle relaxant that is used to treat “discomforts associated with
acute, painful musculoskeletal conditions.” ’128 patent, col. 1, ll. 21-23. Metaxalone was first discovered in the 1960s, and the first patent claiming the method of producing the compound, U.S. Patent No. 3,062,827, issued in 1962 to A.H. Robins Company. A.H. Robins began selling metaxalone under the brand name Skelaxin in 1962. Elan eventually acquired the rights to Skelaxin and sold those rights in 2003 to King, which now markets and sells Skelaxin.

On August 31, 2004, Eon filed an Abbreviated New Drug Application (“ANDA”) for a generic 800 mg metaxalone tablet. Eon filed with the ANDA a patent certification … which alleged that none of the claims of the ’128 patent would be infringed by the manufacture, use, or sale of Eon’s generic 800 mg metaxalone tablet, and that all the claims of the ’128 patent are invalid. In response … King filed suit against Eon under the Hatch-Waxman Act. The complaint accused Eon of infringing the ’128 and ’102 patents. King’s action was consolidated with an earlier, related action … that Elan filed in 2001 against Eon after Eon filed an ANDA for a generic 400 mg metaxalone tablet. Elan asserted the ’128 patent in the 400 mg Action, but the case was dismissed after Eon withdrew its 400 mg ANDA. …

The ’128 patent, titled “Method for Increasing the Bioavailability of Metaxalone,” issued on June 18, 2002 and was initially assigned to Elan. Elan subsequently assigned the ’128 patent to King in 2003. The patent discloses a method of “increasing the bioavailability of metaxalone by administration of an oral dosage form with food.” The claimed invention is the result of “the unexpected finding that administration of metaxalone with food increases both the rate and extent of absorption via the oral dosage form in human subjects.”

The ’128 patent has three independent claims, claims 1, 9, and 17. Claim 1 claims “a method of increasing the oral bioavailability of metaxalone” by “administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.” Claim 9 claims a method for increasing “the rate and extent of absorption *** of metaxalone *** in the bloodstream” by “administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.” Claim 17 claims a method similar to claim 1, but limits the effective amount of metaxalone to between 400 and 800 mg and defines an increase in bioavailability as “an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.”

Dependent claims 2, 3, 10, and 11 specify that the “therapeutically effective amount” of metaxalone is “200 mg to 900 mg” (claims 2 and 10) or “400 mg to 800 mg” (claims 3 and 11). Dependent claims 4-6, 12-14, and 18-20 specify specific times for administering the metaxalone relative to the consumption of food, either thirty minutes prior to two hours after consumption of food (claims 4, 12 and 18), “substantially at the same time” as consumption of food (claims 5, 13 and 19), or up to one hour after consumption of food (claims 6, 14 and 20). Dependent claims 7 and 15 limit the dosage to a tablet form, and dependent claims 8 and 16 limit the dosage to a “unit dosage form.” Dependent claim 21 claims the method of claim 1 with the additional limitation of “informing” the patient that taking metaxalone with food will increase the drug’s bioavailability, and dependent claim 22
claims the method of claim 1 with the additional limitation that “the metaxalone is from a container with printed labeling advising” that taking metaxalone with food will increase the drug’s bioavailability.

The ’102 patent issued on January 27, 2004 and is titled “Methods of Using Metaxalone in the Treatment of Musculoskeletal Conditions.” Elan assigned the application that resulted in the ’102 patent to King in 2003. Like the ’128 patent, the ’102 patent discloses a method of “increasing the bioavailability of metaxalone by administration of an oral dosage form with food.” Independent claim 1 claims a method for using metaxalone in the treatment of musculoskeletal conditions comprising both “providing” a patient with a “therapeutically effective amount of metaxalone” and “informing” the patient that taking metaxalone with food increases the bioavailability of the drug. Claims 2 through 5 depend from claim 1 and either specify the “therapeutically effective amount” as 200 mg to 900 mg (claim 2) or 400 mg to 800 mg (claim 3), or limit the dosage to a tablet form (claim 4) or a “unit dosage form” (claim 5).

Independent claim 6 claims a “method of using metaxalone in the treatment of musculoskeletal conditions” consisting of “informing a patient” that taking metaxalone with food increases the bioavailability of the drug compared to taking metaxalone without food. Independent claim 7 claims a “method of using metaxalone in the treatment of musculoskeletal conditions” by “obtaining metaxalone from a container providing information that administration of metaxalone with food” increases the drug’s bioavailability and “ingesting the metaxalone with food.”

Independent claim 8 claims a “method of using metaxalone in the treatment of musculoskeletal conditions” comprising both administering metaxalone with food and informing the patient that such administration increases the bioavailability of the drug. Dependent claims 9 through 11 limit claim 8 to metaxalone from a container with printed information concerning the increased bioavailability of the drug (claim 9), metaxalone in a tablet form (claim 10), and 400 mg of metaxalone (claim 11). Claims 12, 13, and 14 depend from claim 9 and limit the printed label to stating certain percentage increases in the bioavailability of metaxalone. Finally, claim 15 depends from claim 8 and limits the metaxalone to a 400 mg tablet with a printed label that states certain percent-age increases in the bioavailability of the metaxalone.


Fathie II describes a clinical study in which patients were given 800 mg of metaxalone to be taken three to five times a day. The article notes that several patients complained of nausea and that “nausea might have been less prominent if the medication had been taken with food.”

Albanese is a reference guide for registered nurses. The guide discloses that metaxalone is available in 400 mg tablets and recommends a dosage range of 800
mg three to four times daily. The guide also notes that “[a]dministration with meals will help reduce gastric upset.”

Abrams is another reference guide for registered nurses. The reference guide discloses providing patients with 800 mg of metaxalone three or four times daily for not more than ten consecutive days. The reference guide also instructs nurses to give metaxalone “with milk or food” in order to “decrease gastrointestinal distress.”

Eon moved for summary judgment of invalidity. Eon’s motion asserted that all claims of the ’128 and ’102 patents were either anticipated by or obvious in light of the prior art. The district court granted Eon’s motion.

Discussion
A. Legal Standards

Under 35 U.S.C. § 102 a claim is anticipated “if each and every limitation is found either expressly or inherently in a single prior art reference.” Celeritas Techs. Ltd. v. Rockwell Int’l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998). “[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation.” Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in original). …

B. Analysis

The district court considered and invalidated all thirty-seven claims of the ’128 and ’102 patents, and King appeals thirty-six of those findings. We begin, as the district court did, with the ’128 patent and then turn to the ’102 patent.

I. The ’128 Patent

a. Claim 1

Claim 1 is an independent claim requiring the administration of “a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.” Claim 1 contains a preamble, which King argues is the claim’s source of novelty. The preamble reads, “[a] method of increasing the bioavailability of metaxalone to a patient receiving metaxalone therapy.” According to King, while the prior art may disclose taking metaxalone with food, it does not disclose increasing the bioavailability of the drug.

In its summary judgment opinion, the district court rejected King’s argument and found claim 1’s preamble inherently anticipated. According to the district court, an increase in the bioavailability of metaxalone is an inherent property of taking metaxalone with food, which is disclosed in each of Fathie II, Albanese, and Abrams.

On appeal, King argues the district court erred because Eon did not provide any evidence or expert testimony that the prior art would necessarily result in an increase in metaxalone’s bioavailability. King argues that the prior art’s disclosure (taking metaxalone with food to reduce gastric discomfort) is vague as to the conditions under which the food was administered such that it was improper for the district court to assume that an increase in bioavailability was necessarily disclosed.
Specifically, King contrasts the precise conditions on food consumption disclosed in the ’128 patent with the vague conditions disclosed in Fathie II, Albanese, and Abrams. For further support, King cites its own expert reports which conclude that “even a disclosure of taking metaxalone with food would not inherently disclose increasing the bioavailability of metaxalone.”

As an initial matter, King’s attempt to link an increase in metaxalone’s bioavailability to specific food conditions is untenable. While the ’128 patent’s written description discloses specific conditions for food consumption, its claims only recite taking metaxalone “with food.” It would be improper to limit the broad terms used in the ’128 patent’s claims to the specific food conditions disclosed in the written description. See Kara Tech, Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”). Moreover, the written description in no way suggests that the specific food conditions disclosed were necessary for increasing metaxalone’s bioavailability. Rather, the written description teaches that the claimed increase in metaxalone’s bioavailability can be achieved through the consumption of “a meal, such as breakfast, lunch or dinner.” ’128 patent, col. 2, ll. 37-38. The district court was therefore correct in finding that “the ’128 patent does not identify any additional conditions that must be present for the food effect to occur. Rather, it occurs naturally in most people when they take metaxalone with food.” See also Verdegaal Bros., Inc. v. Union Oil Co. of California, 814 F.2d 628, 632 (Fed. Cir. 1987) (holding reliance on non-claimed distinction between prior art method and claimed method “inappropriate” and insufficient to save the claim from inherent anticipation).

As for the merits of King’s argument, we first note that Fathie II, Albanese, and Abrams each disclose administering metaxalone “with food” or “with meals” to treat musculoskeletal conditions. Fathie II, published thirty-six years prior to the filing of the ’128 patent, teaches administering metaxalone “with food” to reduce nausea. Albanese, published nineteen years prior to the filing of the ’128 patent, teaches administering metaxalone “with meals” to “reduce gastric upset.” And, Abrams, published six years prior to the filing of the ’128 patent, teaches administering metaxalone “with milk or food” to “decrease gastrointestinal distress.”

We have held that “[i]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.” In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990). Such newly discovered benefits are not patentable because they are inherent in the prior art. See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001). While inherent anticipation “may not be established by probabilities or possibilities,” In re Oelrich, 666 F.2d 578, 581 (CCPA 1981), if “the [prior art’s] disclosure is sufficient to

2 Participants in the study were given fifteen minutes to eat the following before administration of the metaxalone: 2 eggs (fried in butter), 2 strips of bacon, 2 slices of toast with butter, 4 oz. of hash brown potatoes, and one glass whole milk (8 oz.). See ’128 patent, col. 3, ll. 14–25.
show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well-settled that the disclosure should be regarded as sufficient,” *id.* (alterations added).

According to the ’128 patent, the natural result of taking metaxalone with food is an increase in the bioavailability of the drug. The prior art discloses taking metaxalone with food, but not the natural result of this process. However, because the prior art methods in their “normal and usual operation *** perform the function which [King] claims in [the ’128 patent], then such [patent] will be considered, to have been anticipated by the [prior art].” *In re Ackenbach*, 45 F.2d 437, 439 (CCPA 1930) (alterations added). As taught by the ’128 patent, the only steps required to increase metaxalone’s bioavailability are (1) ingesting metaxalone (2) with food. These steps are undeniably disclosed by the prior art. An increase in metaxalone’s bioavailability is, therefore, an inherent aspect of the prior art. In other words, the increase in metaxalone’s bioavailability is the “natural result flowing from the [prior art’s] explicitly explicated limitations.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001) (alterations added); see also *MEHL/Biophile Int’l Corp. v. Milgram*, 192 F.3d 1331, 1336 (Fed. Cir. 1999) (“[T]o the extent the embodiment in the patent achieves [the limitation], so does the [prior art].”) (alterations added). Accordingly, claim 1’s preamble is inherently anticipated.

King’s experts’ opinions that “even a disclosure of taking metaxalone with food would not inherently disclose increasing the bioavailability of metaxalone,” do not undermine our analysis. To anticipate, the prior art need only meet the inherently disclosed limitation to the extent the patented method does. *See Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003) (“[A] prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention.”). Because the ’128 patent discloses no more than taking metaxalone with food, to the extent such a method increases the bioavailability of metaxalone, the identical prior art method does as well. As the district court aptly stated, “to inherently anticipate, the prior art need only give the same results as the patent, not better.”

For the foregoing reasons, the district court’s inherent anticipation analysis was proper. The preamble to claim 1 is inherently anticipated. To hold otherwise would remove from the public a method of treating muscle pain that has been performed for decades. *See Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999) (“The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.”). Accordingly, the district court’s finding that claim 1 is anticipated is affirmed.

Because we reject King’s argument that claim 1’s preamble is novel, we also affirm the district court’s findings of invalidity as to claims 2, 3, 8-11, and 15-17. For these claims, King’s sole argument on appeal was that their incorporation of claim 1’s preamble (claims 2, 3, 7, and 8) or their recitation of a similar preamble (claims 9-11 and 15-17) made the claims novel. Like claim 1, these claims are anticipated because their sole source of novelty is inherently disclosed by the prior art.
b. Claims 4-6, 12-14, and 18-20

Claims 4-6 depend from claim 1. The claims limit the time frame in which the patient must ingest the metaxalone in relation to consuming food. Claim 4 limits the time frame to “30 minutes prior to 2 hours after consumption of the food,” claim 5 limits it to “substantially at the same time,” and claim 6 limits it to “immediately after the consumption of food up to 1 hour after.” Fathie II, Albanese, and Abrams respectively disclose administering metaxalone “with food,” “with meals,” and “with food or milk.”

On appeal, King argues that none of the claims’ specific timeframe requirements is disclosed in Fathie II, Albanese, or Abrams. Yet, according to King’s own experts, “with food” could mean taking metaxalone “1 hour prior to up to about 2 hours after eating.” (Decl. of Dr. Elia). Under this common-sense definition of “with food,” the prior art discloses a timeframe for ingesting metaxalone in relation to consuming food that falls within the timeframes claimed by claims 4-6. The district court’s finding that claims 4-6 are anticipated is therefore affirmed. See Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (“[It is] an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.”); Fresenius USA, Inc. v. Baxter Int’l, Inc., 582 F.3d 1288, 1298 (Fed. Cir. 2009).

Claims 12-14 and 18-20 contain identical timeframe requirements. The district court invalidated these claims for the same reasons it invalidated claims 4-6. We therefore affirm …

c. Claim 21

Claim 21 depends from claim 1 and adds the limitation “informing the patient that administration of a therapeutically effective amount of metaxalone in a pharmaceutical composition with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.” The district court invalidated claim 21 …

…

Because we have already determined that independent claim 1 is anticipated, dependent claim 21’s sole potential source of novelty is the “informing” limitation. King argues that the district court committed legal error because it never found the “informing” limitation disclosed in the prior art, which it was required to do. See Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999 (Fed. Cir. 2006) (“Anticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently.”). Eon tacitly concedes that the district court never expressly found the “informing” limitation disclosed in the prior art, but contends such a finding was unnecessary because the nonpatentable “informing” limitation cannot breathe novelty into an otherwise anticipated method.

The specific question before us is whether an otherwise anticipated method claim becomes patentable because it includes a step of “informing” someone about the existence of an inherent property of that method. We hold it does not. The “informing” limitation adds no novelty to the method, which is otherwise anticipated
by the prior art. In other words, in light of our holding that the method of taking metaxalone with food to increase the drug’s bioavailability, as recited in claim 1, is not patentable, it readily follows that claim 21, which recites the same method with the sole additional step of informing the patient about this increase in bioavailability, is not patentable.

In an analogous context, we have held that “[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (alterations added). In such cases, we have recognized that the printed matter is not independently patentable, but have cautioned that the limitation must not be excised from the claim. See id. at 1385 (“[T]he board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole.”) (alterations added). Instead, the relevant question is whether “there exists any new and unobvious functional relationship between the printed matter and the substrate.” Id. at 1386 (citing In re Miller, 418 F.2d 1392, 1396 (CCPA 1969)). The rationale behind this line of cases is preventing the indefinite patenting of known products by the simple inclusion of novel, yet functionally unrelated limitations. See In re Ngai, 367 F.3d [1336,] 1339 [(Fed. Cir. 2004)].

Although these “printed matter” cases involved the addition of printed matter, such as written instructions, to a known product, we see no principled reason for limiting their reasoning to that specific factual context. See In re Ngai, 367 F.3d at 1338-39; In re Gulack, 703 F.2d at 1385-87. Rather, we believe that the rationale underlying these cases extends to the situation presented in this case, wherein an instructional limitation is added to a method, as opposed to a product, known in the art. Thus, the relevant inquiry here is whether the additional instructional limitation of claim 21 has a “new and unobvious functional relationship” with the known method of administering metaxalone with food. See In re Ngai, 367 F.3d at 1338 (quoting In re Gulack, 703 F.2d at 1386).

King contends that there is a functional relationship between the “informing” limitation and the method. Specifically, at oral argument, King’s counsel argued that the “informing” limitation increases the likelihood that the patient will take metaxalone with food, thereby increasing the efficiency of the method. See Oral Arg. at 7:30-8:26. This relationship, however, is not functional. Informing a patient about the benefits of a drug in no way transforms the process of taking the drug with food. Irrespective of whether the patient is informed about the benefits, the actual method, taking metaxalone with food, is the same. In other words, the “informing” limitation “in no way depends on the [method], and the [method] does not depend on the ['informing’ limitation].” In re Ngai, 367 F.3d at 1339 (alterations added). “It is not invention to perceive that the product which others had discovered had qualities they failed to detect.” Gen. Elec. Co. v. Jewel Incandescent Lamp Co., 326 U.S. 242, 249 (1945). Accordingly, we affirm the district court’s finding that claim 21 is invalid, but on the alternative ground that the claim is anticipated by the prior art.
d. Claim 22

Claim 22 is closely related to claim 21. Claim 22 depends from claim 1 and limits claim 1’s method to situations “wherein the metaxalone is from a container with printed labeling advising that administration with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.” The district court, relying on this court’s printed matter precedent as articulated in In re Ngai, found the claim anticipated by Fathie II, Albanese, and Abrams.

Because it depends from claim 1, the printed label limitation is claim 22’s only potential source of novelty. However, as the district court correctly found, the printed label limitation falls squarely within our printed matter cases discussed above with respect to claim 21. While ostensibly a method claim, the potentially novel aspect of claim 22 concerns a printed label on a product. Like claim 21’s “informing” limitation, the printed label is not functionally related to either the product within the method claim or the method claim as a whole. Therefore, the district court was correct in finding the claim anticipated. See In re Ngai, 367 F.3d at 1339.

King attempts to avoid In re Ngai by limiting that case to product claims. According to King, because claim 22 is a method claim, In re Ngai, which addressed a product claim, is not applicable. During our discussion of claim 21, we rejected the notion that In re Ngai’s holding should be limited solely to product claims. Accordingly, we reject King’s argument and affirm the district court’s finding that claim 22 is anticipated.

We also affirm the district court’s invalidation of claims 7, 9, and 12-15 of the ’102 patent, which are nearly identical to claim 22 of the ‘128 patent. The district court invalidated these claims for the same reasons it invalidated claim 22. On appeal, King argues claims 7, 9, and 12-15 of ’102 patent are novel for the same reasons claim 22 was allegedly novel, i.e., their incorporation of a printed label limitation. For the reasons discussed above, we reject this argument and affirm the district court’s invalidation of claims 7, 9, and 12-15 of ‘102 patent.

II. The ’102 Patent

a. Claim 1

Claim 1 of the ’102 patent is an independent claim, which claims a “method of using metaxalone in the treatment of musculoskeletal conditions” comprising both “providing the patient with a therapeutically effective amount of metaxalone” and “informing the patient that administration with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.” …

As we discussed with respect to claim 21 of the ’128 patent, … claim 1’s sole source of novelty is the “informing” limitation. Because this limitation is not functionally related to the otherwise anticipated method, the claim is anticipated. Accordingly, we affirm the district court’s finding that claim 1 is invalid … on the alternative ground that the claim is anticipated by the prior art.

Because we reject King’s argument that claim 1’s “informing” limitation is novel, we also affirm the district court’s finding of invalidity as to dependent claims 2
through 4 and independent claim 8 and its dependent claims 10 and 11. For these claims, King argued on appeal that their incorporation of the “informing” limitation (claims 2-4) or their recitation of a similar limitation (claims 8, 10, and 11) made the claims novel. For the reasons discussed above, we reject King’s argument … .

…

Statutory Bars

Mueller’s Patent Law: 197-211

Pronova BioPharma Norge v. Teva Pharm.

549 Fed. Appx. 934 (Fed. Cir. 2013)

O’Malley, Judge:

This patent infringement suit arises from Abbreviated New Drug Applications (“ANDAs”) filed by Teva Pharmaceuticals and Par Pharmaceutical. Through their ANDAs, Appellants seek to market generic versions of Lovaza, a pharmaceutical product marketed by Plaintiff Pronova BioPharma Norge. Following a bench trial, the [court] entered final judgment for Pronova, holding that U.S. Patent No[.] 5,656,667 was infringed, not proven invalid as ... anticipated under § 102(b) by prior public use ... . Teva and Par appeal those four rulings. Because we find that Pronova’s predecessor, Norsk Hydro, made the inventions claimed in the ’667 patent publicly accessible before the statutory bar date, constituting an invalidating public use pursuant to § 102(b), we reverse. This ruling renders moot all remaining issues regarding the ’667 patent. …

I. Background

A. Claimed Technology

Pronova is the holder of approved New Drug Application (“NDA”) No. 121654 for Lovaza and is the owner by assignment of the patents-in-suit. The patents-in-suit are listed in the [FDA’s] Approved Drug Products with Therapeutic Equivalence Evaluations for Lovaza. Lovaza is the first and only fish-oil derived prescription drug approved by the FDA. It contains fish-oil components in concentrated amounts. The drug is indicated to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, i.e., high levels of triglycerides. Since its entry into the market in 2005, Pronova has sold large amounts of Lovaza in the U.S. market, with U.S. sales amounting to over $2.3 billion as of August 2010.

Starting in the 1970s, medical studies established the medical benefits of fish oil for treating heart disease. A 1972 Danish study reported that Greenland Eskimos, whose diet is high in fish (and thus high in fat), had very low rates of heart disease. The study postulated that the fish fat in their diet, which has a high concentration of polyunsaturated fatty acyl components, had beneficial properties. Subsequent research in the 1980s concluded that two components, eicosapentaenoic acid (“EPA”) and docosahexaenoic acid (“DHA”), two omega-3 fatty acids, were the active agents giving fish oil its beneficial properties. Thus, starting in the 1980s, fish oil capsules containing, among other components, EPA and DHA, have been used to treat hypertriglyceridemia.
… The asserted claims are drawn to pharmaceutical compositions or methods of using such compositions. The claims recite specific concentrations of five fish-oil derived components: EPA, DHA, heneicosapentaenoic acid (“HPA”), docopentaenoic acid (“DPA”), and arachidonic acid (“AA”). All except AA are omega-3 fatty acids; AA is an omega-6 fatty acid. The claimed compositions have high concentrations of EPA and DHA, the active ingredients in the formulation (“the major components”), and low concentrations of the other three fatty acid components, AA, HPA, and DPA (“the minor components”).

B. Lower Court Proceedings

Teva and Par separately filed an ANDA seeking to market a generic version of Lovaza … . Their ANDAs contained paragraph IV certifications indicating that the ’667 [patent was] not infringed or w[as] invalid. In response, Pronova filed lawsuits against Teva and Par … . The district court held a bench trial for the consolidated cases from March 30 to April 6, 2011. After post-trial briefing, it held that Pronova proved that Teva’s and Par’s ANDA products will infringe all the asserted claims and Teva and Par failed to establish invalidity of the asserted claims … .

Specifically, Appellants asserted, among other things, that the asserted claims of the ’667 patent were invalid under 35 U.S.C. § 102(b) for public use prior to the statutory bar date. The parties agreed that, on September 8, 1987, Norsk Hydro, Pronova’s predecessor, sent Dr. Victor Skrinska (“Skrinska”) of St. Vincent Charity Hospital liquid vials of its “K-80” ethyl ester composition. Those samples, Pronova concedes, were produced by Norsk Hydro in a batch numbered 222 (“Batch 222”), which met all the limitations of the asserted claims of the ’667 patent. Appellants argued to the district court that Norsk Hydro, by providing Skrinska samples and disclosing their content, made an invalidating public use of the claimed invention. They also argued that Skrinska himself made invalidating public uses of the samples when he tested them to confirm their content, discussed them with colleagues, and administered capsules to himself and others.

… The court pointed to testimony and documents indicating that Norsk Hydro sent Skrinska two 100 mL liquid samples of Batch 222, and Skrinska’s testimony that he believes Norsk Hydro subsequently sent him 500 to 1000 capsules of concentrated fish oil. Regarding the first shipment, the district court acknowledged that Skrinska tested the two samples to confirm (and did confirm) their content, but, the court concluded that, beyond this, “Appellants do not point to any particular ‘use’ [by Skrinska] of the two Batch 222 liquid vials.” Again, while no conclusion of law expressly says so, the court apparently agreed with Pronova that an invalidating use of a pharmaceutical compound must be for the purposes identified in the patents-in-suit—to treat hypertriglyceridermia. Regarding the second shipment (i.e., the capsules), the district court noted that Skrinska had trouble remembering details surrounding the shipment, such as whether anyone other than Norsk Hydro sent him fish oil capsules or specific data from assays performed on the capsules. The lower court also recounted Skrinska’s testimony in which he detailed the use of the capsules in a six-person, two week study, but it noted that no corroborating documentary evidence of this study was adduced at trial. The district court ultimately discre-
C. Arguments on Appeal

On appeal, Teva asserts the testing which Skrinska performed constitutes an invalidating public use because, in its view, any use of a claimed invention can be invalidating. An invalidating public use need not be the intended use of the invention disclosed or claimed in the patent as long as the invention is fully disclosed without restriction. It was thus unnecessary for Skrinska to use the samples to treat high levels of triglycerides, Teva maintains. Teva also discounts the district court’s credibility finding regarding Skrinska’s testimony, arguing that finding did not pertain to the testing of the vials (but only to the testing and use of the capsules) and, that the vial testing was corroborated by various forms of documentary and circumstantial evidence.

...Pronova responds that, to be invalidating under § 102(b), an invention must be used by someone other than the inventor for its intended purpose. Merely sending samples is insufficient, Pronova believes, since making shipments is not the use intended in the patents. And, even if the invention is put to a commercial use, such use can only be invalidating, Pronova asserts, if it is for the invention’s intended purpose. Thus, Pronova claims that, because no one other than Skrinska claimed to have used the samples they received to treat hypertriglyceridemia, and that aspect of Skrinska’s testimony was discredited, there can be no invalidating public use; in Pronova’s view disclosing its products to others and “analytical testing” of those products can never constitute a public use of the inventions disclosed in the ’667 [patent].

We take these arguments up below, and ultimately agree with Appellants, finding Pronova’s view of what constitutes public use under § 102(b) too narrow.

II. Legal Standard

...Whether a patent is invalid due to public use under [the 1952 Act version of] § 102(b) is a question of law based on underlying questions of fact. Netscape Commc’ns Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002). We review the lower court’s ultimate legal determination de novo, Adenta GmbH v. OrthoArm, Inc., 501 F.3d 1364, 1369 (Fed. Cir. 2007), but, following a bench trial, we review its underlying findings of fact for clear error, Preston v. Marathon Oil Co., 684 F.3d 1276, 1287-88 (Fed. Cir. 2012).

“[T]he policies underlying the public use bar inform its scope and *** one such policy is discouraging the removal, from the public domain, of inventions that

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5 While Pronova contends in its briefing here that Skrinska’s testimony regarding analytical testing of the liquid vial batches was uncorroborated and, thus, should be disregarded, it does not appear Pronova made this argument at trial. In any event, we read the trial court’s factual findings to credit this aspect of Skrinska’s testimony and find that conclusion well-supported by the evidence at trial.
the public reasonably has come to believe are freely available.” *Dey, L.P. v. Sunovion Pharm.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013). “A bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting.” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). Regarding the first requirement for the public use bar to attach, we explained in *Invitrogen* that either public accessibility or commercial exploitation would qualify as “public use:”

The proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. Commercial exploitation is a clear indication of public use, but it likely requires more than, for example, a secret offer for sale. Thus, the test for the public use prong includes the consideration of evidence relevant to experimentation, as well as, *inter alia*, the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation.

*Id.* at 1380.

The Supreme Court explained the “ready for patenting” requirement, in the context of the § 102(b) on sale bar, in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67-68 (1998). “That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.” 525 U.S. at 67-68. Our court subsequently held that this requirement applies equally to the public use bar of § 102(b). *Invitrogen*, 424 F.3d at 1379.

III. Analysis

In this case, there is no dispute regarding the “ready for patenting” requirement—the parties agree that Norsk Hydro sent samples to Skrinska meeting the limitation of the asserted claims of the ’667 patent.7 That is, the invention was reduced to practice. The dispute on appeal concerns the first requirement of the statutory bar, whether the invention was in “public use.” We hold that Norsk Hydro provided public access to its invention when it sent samples to Skrinska with no confidentiality restrictions; the Appellants proved by clear and convincing evidence that the invention was in “public use.”

A. Public Accessibility Inquiry

“Our cases have provided considerable guidance as to what it means to be ‘accessible to the public.’” *Dey*, 715 F.3d at 1355. Thus, “public use may occur when ‘a completed invention is used in public, without restriction.’” *Id.* (quoting *Allied

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7 Because ultimately we hold that Norsk Hydro made an invalidating use of the inventions described in the asserted claims of the ’667 patent when it sent at least two liquid samples to Skrinska, we focus on only that use—the shipment and testing of the liquid vials—in our analysis. It is unnecessary for us to reach the other purportedly invalidating uses which Appellants assert.
Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995)). “[A]n agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a ‘public use’ where there is not commercial exploitation.” Invitrogen, 424 F.3d at 1382. Similarly, a disclosure of some aspects of an invention, but not all, will likely preclude a finding of public use. See, e.g., W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1549 (Fed. Cir. 1983) (reversing § 102(b) invalidation, in part, because “looking at the machine in operation does not reveal whether it is stretching, and, if so, at what speed. Nor *** whether the crystallinity and temperature elements of the invention set forth in the claims are involved.”).

1. Restrictions on Use

In the seminal case Egbert v. Lippmann, 104 U.S. 333, 336 (1881), the Supreme Court articulated the principal inquiry regarding public use: Was the invention’s use public in the sense that it was made available to others with no limitation or restriction? Specifically in Egbert, an inventor made several embodiments of his invention, springs to be used with a women’s corset, and gave them to a friend who wore them under her clothes for several years. Egbert, 104 U.S. at 335. Despite the essentially concealed nature of the friend’s use, the Supreme Court invalidated the patent:

If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person. Id. at 336. The inquiry is not whether the third person to whom an invention is disclosed makes an open and obvious use of it, but whether the inventor himself has made a use of his invention which is “public” because it was given to a member of the public without restriction. Given the nature of the inquiry, our case law understandably focuses on the limitations, restrictions, or secrecy obligations associated with a purported public use. See, e.g., Dey, 715 F.3d at 1355; Netscape, 295 F.3d at 1321. We have explained that “whether an invention is accessible to the public or reasonably believed to be freely available depends, at least in part, on the degree of confidentiality surrounding its use.” Dey, 715 F.3d at 1355. The degree of confidentiality necessary to avoid a finding of public use naturally depends on the circumstances. Id.

To analyze the degree of confidentiality surrounding a purported public use, we have also focused on the amount of control which the discloser retains over the invention during the uses in question. For example, in Lough v. Brunswick Corp., 86 F.3d 1113, 1121 (Fed. Cir. 1996), we invalidated a patent despite an inventor’s argument that the uses were experimental, because he had given the invention—seals for boat motors—to several friends who, in turn, installed and tested one on a boat, which they later sold. After the sale, neither the inventor nor the friends “knew what happened with either the prototype or the demonstration boat after the boat was sold,” so the inventor “did not maintain any supervision and control over the seals during the alleged testing.” Id. Similarly, in Eolas Technologies Inc. v. Microsoft Corp., 399 F.3d 1325, 1334 (Fed. Cir. 2005), we found that a demonstration of the invention to “two Sun Microsystems employees without confidentiality agreements”
was an invalidating public use under § 102(b), even though there was no evidence that those employees personally “used” the invention. And, in *Beachcombers Int’l, Inc. v. Wildewood Creative Prods.*, 31 F.3d 1154, 1159-60 (Fed. Cir. 1994), we affirmed a jury verdict finding public use of a patented device under § 102(b) based on evidence that the designer and developer demonstrated a prototype at a party for her guests to view. On the other hand, in *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1263-67 (Fed. Cir. 1986), we upheld a patent even though the inventor had showed prototypes of the invention, a threedimensional puzzle, to several friends and his employer over the course of five years. We upheld the lower court’s findings that the inventor “at all times retained control over the puzzle’s use and the distribution of information concerning it,” and he “retained control even though he and [the employer] had not entered into any express confidentiality agreement.” *Id.* at 1266.

Also among the circumstances of the disclosure upon which we have focused is the sophistication of those to whom disclosure was made. As we recently explained in *Dey*, while a public use might not arise where disclosure is limited to a small number of uninformed observers, “even limited disclosure to those who are skilled enough to know, understand, and ‘easily demonstrate the invention to others,’ may mean that there was no reasonable expectation of secrecy and that the invention was therefore in public use.” *Dey*, 715 F.3d at 1356 (citing *Netscape*, 295 F.3d at 1321).

2. Scope of Disclosure

Even where a disclosure is unrestricted, it will not be an invalidating public use, unless the patent challenger establishes that all claimed aspects of the invention were made public. See, *e.g.*, *Dey*, 715 F.3d at 1357. Two of our recent cases illustrate this point. In *Dey*, for example, we held that the alleged infringer was not entitled to summary judgment of invalidity due to prior public use. *Id.* The purported public use was the defendant’s own clinical trial of the allegedly infringing product. *Id.* Because only the clinical trial administrator, not the subjects taking the medication, was made aware of the invention’s claimed formulation and stability characteristics, and the administrator had signed a pledge of confidentiality, we held that “a finder of fact could conclude that the study was conducted with a reasonable expectation of confidentiality as to the nature of the formulations being tested, [such that] summary judgment on the public use issue was inappropriate.” *Id.* (emphasis added). A fact finder could so conclude even though the subjects did not likewise sign a confidentiality pledge because “they were given incomplete descriptions of the treatment formulation.” *Id.*

Likewise, in *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007), we reversed a lower court judgment invalidating a patent where certain disclosures did not reveal all aspects of the claimed invention, and another disclosure, which did so, was subject to a non-disclosure agreement. Specifically, the invention was an ergonomic keyboard and the claims required that the device transmit information. See U.S. Patent No. 5,178,477, col. 7, ll. 46-48 (“An ergonomic keyboard input device for the transmission of information by a human operator to an electronic system coupled with said device *** ”); U.S. Patent No. 5,332,322, col. 8, ll. 16-31 (“A handheld device for entering information into an
electronic system via a keyboard *** whereby information is entered into an electronic system.”). The inventor had shown a prototype of the invention to potential investors, but the prototype was not plugged into a computer during these displays. *Id.* at 1379. He also made the invention available to a third-party to perform testing, which did involve the transmission of information, but that third party had signed a confidentiality agreement. *Id.* We found no public use from either disclosure:

All disclosures, except for the one-time typing test, only provided a visual view of the new keyboard design without any disclosure of the [prototype’s] ability to translate finger movements into actuation of keys to transmit data. In essence, these disclosures visually displayed the keyboard design without putting it into use. In short, the [prototype] was not in public use as the term is used in § 102(b) because the device, although visually disclosed and only tested one time with a NDA signed by the typing tester, was never connected to be used in the normal course of business to enter data into a system.

*Id.* Our precedent thus establishes firmly that all aspects of the claimed invention must be disclosed for the § 102(b) public use bar to apply. See also *Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc.*, 134 Fed. Appx. 425, 431 (Fed. Cir. 2005) (“Janssen correctly argues, however, that because the composition of F12 (including the beads and the size of the cores contained in the capsule) was never released to the doctors or the subjects of the trials, this fact weighs in favor of a finding that the use was not public.”); *W.L. Gore & Assoc.*, 721 F.2d at 1549 (reversing lower court judgment invalidating method claims under § 102(b) because there was “no evidence that a viewer of [a] machine could thereby learn anything of which process, among all possible processes, the machine is being used to practice”).

With these principles in mind, we turn to the allegedly invalidating use at issue here. Because we find that Norsk Hydro sent samples of the invention claimed in the ’667 patent to Skrinska at St. Vincent Charity Hospital without restriction and Skrinska thereafter tested the samples, we hold that Norsk Hydro put its invention to an invalidating public use.

B. Norsk Hydro’s Actions

Sometime in 1987, Norsk Hydro visited Skrinska while he was employed at the Cleveland Research Institute and described to him its fish oil products in the hopes of interesting him in conducting studies of or promoting them. On May 15, 1987, Skrinska wrote Norsk Hydro expressing interest in its “purified individual acids,” *i.e.*, omega-3 fatty acids, and in “clinical studies using the mixtures you described in your visit.” In a letter dated November 25, 1986, Sigurd Gulbrandsen of Norsk Hydro informed others within the company of Skrinska’s interest, and the benefits of providing product to Skrinska, who was by then working at St. Vincent Charity Hospital. A consultant had advised Norsk Hydro to “explore the possibility of participating in the St. Vincent Charity diabetes trials” because “St. Vincent Charity Hospital has had a reputation for advanced cardiovascular research” and “certainly represent[s] the most intensive, concentrated—and professionally credible—omega-3 clinic research potential anywhere in the world.” The consultant also believed that
Skrinska “was among the most omega-3-knowledgeable researchers interviewed by [it], with definite interest in the ethyl-esterified triglycerides forms of the Norsk Hydro oils.”

Norsk Hydro followed its consultant’s advice and provided Skrinska with its concentrated fish oil products. In fact, Pronova admits that it “sent Dr. Skrinska a small (100 mL) liquid sample of a K80 product from Batch 163 and a liquid sample of 30% cholesterol-free triglyceride concentrate in July 1987, and then sent him in September 1987 two 100 mL liquid samples of K80 from Batch 222 to replace the first sample.” Br. of Appellee 25. The record contains Norsk Hydro’s correspondence documenting these shipments, including a certificate of analysis for Batch 222, which shows that the product meets the limitations of the asserted claims. Notably, that correspondence makes no mention of any confidentiality restrictions, and Pronova does not argue that any were either requested or given. There was also no agreement restricting use of batches to clinical trials or experiments; Pronova concedes experimental use is not at issue. Skrinska’s testimony on the shipments confirms these events.

Based on the foregoing, we conclude that Norsk Hydro provided Skrinska the invention of the ’667 patent with no secrecy obligation or limitation for his unfeathered use. This access began, at the latest, in September of 1987, when Norsk shipped to Skrinska samples from Batch 222. The shipment made public all aspects of the claimed inventions, since it included a certificate of analysis revealing the composition of the supplied products. The documentary evidence regarding this shipment is unrefuted. Skrinska had access to all aspects of the asserted claims of the ’667 patent. Indeed, he confirmed the disclosed formulation by his own analytical testing.

The use involved here—Norsk Hydro’s shipment of the samples and Skrinska’s analytical testing thereof—is similar to uses we have found invalidating in the past. As in Lough and Beachcombers, described above, Norsk Hydro provided the invention to others under no confidentiality restrictions and kept no track of the third-party’s use. 86 F.3d at 1116; 31 F.3d at 1159-60. Pronova does not even know what Skrinska did with the samples after he received them.

Unlike the cases we cite above where no invalidating public use was found, the public use involved here disclosed all aspects of the claimed invention with no expectation of secrecy. In Dey and Motionless Keyboard, those made aware of all aspects of the claimed invention were under confidentiality restrictions and other disclosures did not reveal all aspects of the claims. See Dey, 715 F.3d at 1357; Motionless Keyboard, 486 F.3d 1379. Here, on the other hand, Norsk Hydro provided a certificate of analysis revealing all the claimed elements without any confidentiality agreement or understanding. As in Netscape, moreover, the disclosure here was made to one highly skilled in the art, with the full ability to know, understand, and fully disclose the invention to others. Indeed, the district court pointed to documents in the record confirming Skrinska’s testimony that he shared information regarding the samples sent to him with other members of the medical community in Cleveland and did not treat that information as confidential.
We are not persuaded by Pronova’s argument that “use” of a pharmaceutical formulation cannot occur until it is used to treat the condition it is intended to counteract, or at least physically ingested. Certainly, where only a partial demonstration of a system’s (or formulation’s) capabilities occurs—as in Motionless Keyboard—or where unsophisticated users are provided a compound with no detail regarding its formulation—as in Dey—there will be no public use. Where, as here, however, a compound is provided without restriction to one highly skilled in the art, that compound’s formulation is disclosed in detail, and the formulation is subject to confirmatory testing, no other activity is needed to render that use an invalidating one. Once the formulation was disclosed in full to Skrinska, without any restriction on its use, it had been released into the “public domain” for purposes of § 102(b).

Accordingly, we hold that Norsk Hydro put the invention in the asserted claims of the ‘667 patent to public use. We reverse the district court ruling to the contrary and hold that the asserted claims of the ‘667 patents are invalid under § 102(b).

... Hamilton Beach Brands v. Sunbeam Prods.
726 F.3d 1370 (Fed. Cir. 2013)

O’Malley, Judge:

Hamilton Beach Brands appeals from the ... granting in part of Sunbeam Products’ motion for summary judgment finding claims 1 and 3-7 of U.S. Patent No. 7,947,928 invalid as anticipated. ... For the reasons below, we affirm the district court’s ruling that the asserted claims are invalid under the on-sale bar.

I. Background

Hamilton Beach and Sunbeam are direct competitors in the small kitchen appliance industry. Both Hamilton Beach and Sunbeam sell competing versions of “slow cookers,” which are electrically heated lidded pots that are used to cook food at low temperatures for long periods. Hamilton Beach is the assignee of the ’928 patent, which is directed to a particular type of portable slow cooker.

The ’928 patent, filed June 4, 2010, is a continuation of U.S. Patent Application No. 12/255,188, which, in turn, is a continuation of U.S. Patent Application No. 11/365,222. The ’222 application was filed on March 1, 2006 and issued on February 3, 2009, as U.S. Patent No. 7,485,831. In other words, the ’928 patent directly at issue in this case is the “grandchild” of the ’831 patent. The ’831 patent disclosed a “portable” slow cooker. The claimed slow cooker included clips used to seal the detachable lid of the device on the housing of the cooker. The sealing action provided by the clips is intended to limit leaking during transport. The ’831 patent provides an image of a preferred embodiment[.]

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8 Because our decision does not depend on Skrinska’s testimony that he used K-80 capsules in a clinical trial, we need not and do not disturb the district court’s credibility finding on that point. That Skrinska received vials, that the formulation of K-80 was fully disclosed, and that Skrinska tested the composition of the vials was fully corroborated and the trial court did not find to the contrary.
The written description provides that at least one “clip” (element 22) is used, among other elements, to seal the lid onto the body of the slow cooker.

Hamilton Beach’s commercial embodiment of its patented invention is the Stay or Go slow cooker. According to Hamilton Beach, the Stay or Go slow cooker was a tremendous commercial success and increased Hamilton Beach’s market share by over 30 percent. In response to Hamilton Beach’s success, Sunbeam, the previous market leader, developed a competing slow cooker called the Cook & Carry. Sunbeam attempted to design around the ’831 patent claims by mounting sealing clips on the lid of the slow cooker rather than on the body.

Hamilton Beach responded to Sunbeam’s introduction of its slow cooker by filing a continuation of the ’222 application, which eventually matured into the ’928 patent. As could be predicted, the ’928 patent claimed a slow cooker with sealing clips on the lid of the slow cooker. During prosecution of the ’928 patent, Hamilton Beach argued that a person of ordinary skill in the art would recognize that placing the clips on the lid was wholly consistent with the original disclosure in the ’222 application. The patent office agreed, and the ’928 patent issued on May 24, 2011. That same day, Hamilton Beach filed suit alleging that Sunbeam’s Cook & Carry slow cooker infringed the ’928 patent.

Hamilton Beach alleged that Sunbeam’s Cook & Carry slow cooker infringed claims 1 and 3-7 of the ’928 patent (“asserted claims”). Claim 1 is representative and provides:

1. A slow cooker for heating of food stuffs, the slow cooker comprising:
   a housing having a base and a side wall extending therefrom to define a heating cavity within the housing, the housing further having a housing rim at a first, free edge of the side wall defining an opening to the heating cavity;
   a heating element disposed within the housing sufficiently proximate the heating cavity to heat the heating cavity;
   a container having a generally hollow interior and a container rim defining an opening for accessing the interior thereof, the interior being capable of retaining the food stuffs therein, the container being shaped and sized to fit within the heating cavity of the housing for heating thereof by the heating element;
   a lid sized and shaped to at least partially cover the opening of the container when placed on the container rim, the lid having a gasket around an outer edge thereof for sealing engagement with the container rim; and
at least one clip mounted between the lid and the side wall of the housing, the at least one clip being an over-the-center clip having a hook and a catch, one of the hook and catch being mounted on one of the lid and side wall of the housing and the other of the hook and catch being mounted on the other of the lid and side wall of the housing, the at least one clip being selectively engageable with the lid and side wall of the housing to selectively retain the lid in sealing engagement with the container rim to inhibit leakage of the food stuffs from the interior of the container, wherein the housing and lid have a vertical height, the at least one clip being disposed entirely within the vertical height of the housing and lid to facilitate storage and transport of the slow cooker when the at least one clip is engaged with the lid and side wall of the housing.

'928 patent, col. 8, ll. 16-49.

Two days after filing suit, Hamilton Beach moved for a preliminary injunction, which the district court denied. A few months later, the district court construed a number of claim terms and then entertained the parties’ motions for summary judgment.

Sunbeam moved the court for summary judgment, contending that its Cook & Carry slow cooker did not infringe the asserted claims. Sunbeam also argued that the asserted claims of the '928 patent were invalid because Hamilton Beach could not claim priority to the '831 patent as it introduced new matter into the '928 written description, which rendered the '928 patent’s claims anticipated under 35 U.S.C. §§ 102(a) and (b). Sunbeam further claimed that Hamilton Beach offered for sale and publicly used the Stay or Go slow cooker, the commercial embodiment of the '831 patent, more than one year prior to the earliest possible filing date, i.e., one year prior to the '831 patent’s application date—March 1, 2006 (the '831 patent’s application date and the earliest possible filing date), rendering the '928 patent claims invalid.

... The district court ... concluded that the '928 patent was invalid because it was not entitled to an earlier filing date than the one listed on its face because Hamilton Beach added new matter when it filed its continuation; therefore, the sales of the Stay or Go slow cooker more than one year before that date served as invalidating sales and uses of the '928 patent under the on-sale and public use bars of 35 U.S.C. § 102(b). And, the district court found that, even if the '928 patent was entitled to an earlier priority date coincident with the '222 application, there were invalidating commercial offers to sell the Stay or Go slow cooker prior to the critical date. ...

II. Discussion

The district court found that Hamilton Beach’s purchase order with its foreign supplier for the Stay or Go amounted to an invalidating commercial offer for sale under the on-sale bar of 35 U.S.C. § 102(b). We agree with the district court that Hamilton Beach’s transaction with its foreign supplier in early 2005 was an offer for sale of a product that anticipated the asserted claims and that the invention was ready for patenting prior to the critical date. As discussed below, therefore, we hold
the asserted claims of the ’928 patent invalid under § 102(b). Consequently, we find the remaining issues on appeal moot.

A. Legal Standard

... The on-sale bar applies when two conditions are satisfied before the critical date: (1) the claimed invention must be the subject of a commercial offer for sale; and (2) the invention must be ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). An actual sale is not required for the activity to be an invalidating commercial offer for sale. *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008). An attempt to sell is sufficient so long as it is “sufficiently definite that another party could make a binding contract by simple acceptance.” *Id.* (citing *Netscape Commc’ns Corp. v. Konrad*, 295 F.3d 1315, 1323 (Fed. Cir. 2002)). “In determining such definiteness, we review the language of the proposal in accordance with the principles of general contract law.” *Id.*

An invention is “ready for patenting” when prior to the critical date: (1) the invention is reduced to practice; or (2) the invention is depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention. *Id.* The on-sale bar is a question of law based on underlying factual findings. See *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1045-46 (Fed. Cir. 2001); see also *Leader Technologies, Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012) (“Whether a patent is invalid for a public use or sale is a question of law, reviewed de novo, based on underlying facts, reviewed for substantial evidence following a jury verdict.”); *Electromotive Division of General Motors Corp. v. Transportation Systems Division of General Electric Co.*, 417 F.3d 1203, 1209-10 (Fed. Cir. 2005) (“Whether an invention was on sale within the meaning of § 102(b) is a question of law that we review de novo based upon underlying facts, which we review for clear error.”).

B. Analysis

Sunbeam contended that Hamilton Beach’s foreign supplier offered to sell the Stay or Go slow cooker, a commercial embodiment of the ’831 and ’928 patents, to Hamilton Beach prior to the relevant critical date of March 1, 2005. The district court agreed and found that the claimed invention in the ’831 and ’928 patents was offered for sale and was ready for patenting before the critical date.

At the outset, there are three important points to note. First, while the trial court found that the relevant critical date for the ’928 patent was June 4, 2009, because the patent included new matter—a finding which would clearly invalidate that patent under § 102(b)—it alternatively found that the on-sale bar applied even if the ’928 patent was entitled to the ’831 patent’s critical date, i.e., March 1, 2005. Because we do not address the trial court’s new matter finding, we employ the earlier critical date in our § 102(b) analysis, a date more favorable to Hamilton Beach. Second, there is no “supplier exception” to the on-sale bar. See *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001). Thus, it is of no consequence that the “commercial offer for sale” at issue in this case was made by Hamilton Beach’s own supplier and was made to Hamilton Beach itself. Finally, a commercial
offer for sale made by a foreign entity that is directed to a United States customer at its place of business in the United States may serve as an invaliding activity. In re Caveney, 761 F.2d 671, 676-77 (Fed. Cir. 1985). It is undisputed that Hamilton’s Beach’s foreign supplier directed its activity to Hamilton Beach within the United States.

1. Commercial Offer for Sale

The district court found that Hamilton Beach’s interaction with its supplier was dispositive regarding whether the patented invention was the subject of a commercial offer for sale. We agree, albeit on slightly different grounds.

On February 8, 2005, Hamilton Beach issued a purchase order to its supplier for manufacture of its Stay or Go slow cookers. Hamilton Beach listed on the purchase order its facility in Tennessee as the shipping address and its office in Virginia as the billing address. Hamilton Beach also listed the specific quantity—almost 2000 units, part number, unit price, and requested delivery date for the slow cookers. On February 25, 2005, the supplier, via email, confirmed that it had received the purchase order and noted that it would begin production of the slow cookers after receiving Hamilton Beach’s release.

As noted by the district court, in the small kitchen appliance industry, such a purchase order is a typical transaction. The transaction involves a manufacturer transmitting a purchase order to a vendor or supplier, with the supplier fulfilling that order by manufacturing the requested items. In that scenario, the manufacturer makes the initial contact, which is an offer to buy. The district court, relying on Linear Tech. Corp. v. Micrel, Inc., 275 F.3d 1040, 1052 (Fed. Cir. 2001), found that an offer to buy a patented invention prior to the critical date amounts to an invalidating sale under § 102(b) as long as the offer is accepted and a binding contract to sell is formed. Id. at 1052.

In Linear Tech., Linear Technology Corporation (“LTC”) created the LT1070 chip, which was “a functioning version of the [claimed] invention.” Id. at 1043-44. Prior to the critical date and release of the chip, LTC’s European distributors submitted purchase orders, or offers to buy, the LT1070. Id. at 1044-45, 1052. Upon receipt of these offers to buy, LTC would create dummy accounts in its sales software until the chip was ready for release, but did not otherwise respond to the buyers’ offers. Id. Once the chip was officially released, LTC customer service representatives would convert the dummy orders into normal orders which it would then accept. Id. The buyers were never required to take any action beyond their initial offers to buy. Id.

Based on those facts, this court stated that “[t]he question is whether LTC accepted [the foreign distributors’ offers to buy] before [the critical date], because if so, then it entered into a binding contract to sell the LT1070 that invalidates the [patent-in-suit].” This court found that, because LTC never communicated acceptance of the distributors’ offers to buy prior to the critical date, there was no completed sale, and, thus, no invalidating sale. Id. at 1052-1054.

Relying on Linear Tech., the district court in this case stated that, if the transactions and communications between Hamilton Beach and its supplier formed a bind-
ing contract, Pfaff’s first prong would be met. The district court then analyzed the communications between Hamilton Beach and its supplier and found that the supplier’s response email in February 2005—prior to the March 1, 2005 critical date—was an objective manifestation of assent that created a binding contract between the parties for sale of the patented product. The parties spend much of their briefing on appeal debating the propriety of this conclusion. While the district court’s conclusion that the claims of the ’928 patent are invalid under § 102(b) was correct, there was no need for the district court to require a binding contract on these facts; Linear Tech. is factually distinguishable, making the lower court’s and parties’ reliance on it misplaced.

After Hamilton Beach sent the February 8, 2005, purchase order to its supplier, the supplier responded that it had received the order and was ready to fulfill it upon Hamilton Beach’s “release.” The email also listed specific details of what the order would entail. These circumstances are notably different than those in Linear Tech., because LTC never responded to the foreign distributors’ offers to buy until after the critical date. The significance of this second communication is important, but not for the precise reason the district court found. As this court has repeatedly stated, a commercial offer for sale under § 102(b) is “one which the other party could make into a binding contract by simple acceptance.” Group One Ltd., 254 F.3d at 1048; see also Lacks Indus., Inc. v. McKeechnie Vehicle Components, USA, Inc., 322 F.3d 1335, 1348 (Fed. Cir. 2003); Dana Corp. v. Am. Axle & Mfg., Inc., 279 F.3d 1372, 1377 (Fed. Cir. 2002).

Hamilton Beach takes aim at the district court’s reliance on the supplier’s response email requesting a “release” before it could begin production of the slow cookers. Hamilton Beach points to the parties’ corporate purchase agreement which allegedly required Hamilton Beach to give a certified review and approval of a final product to its supplier before shipment of any product. Hamilton Beach consequently argues that, because it did not provide that “release” until after the critical date, there was no binding pre-critical date contract, as it says Linear Tech requires. Even accepting all of Hamilton Beach’s factual contentions as true, they are not determinative of whether the communications with its supplier amounted to a commercial offer for sale.

Hamilton Beach’s supplier responded prior to the critical date that it was ready to fulfill the order. In other words, the supplier made an offer to sell the slow cookers to Hamilton Beach. At that point, the commercial offer for sale was made and, under the governing corporate purchase agreement, Hamilton Beach could accept the offer when it so pleased. And, Hamilton Beach concedes, as it must, that, had it provided a “release” any time after it received that email, a binding contract would have been formed. As such, even if the parties had not entered into a binding contract when the supplier responded to the purchase order, the response, nevertheless, was a commercial offer for sale that Hamilton Beach could have made into a binding contract by simple acceptance. This was enough to satisfy Pfaff’s first prong without the need for a binding contract. Grp. One Ltd., 254 F.3d at 1046; see also Lacks In-
2. Ready for Patenting

A product is “ready for patenting” for purposes of the on-sale bar under § 102(b) if the claimed invention is: (1) reduced to practice; or (2) depicted in drawings or other descriptions “that were sufficiently specific to enable a person skilled in the art to practice the invention.” *Pfaff*, 525 U.S. at 67-68; see also *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1332-34 (Fed. Cir. 1998) (holding that drawings depicting and samples of the claimed invention were sufficiently definite to enable a person of skill in the art to practice the invention). The district court explained that Hamilton Beach held precritical date meetings with many of its retail customers’ buying agents and presented detailed descriptions and depictions of the Stay or Go slow cooker. At these meetings and presentations, Hamilton Beach showed and distributed Computer Aided Design (“CAD”) drawings depicting the Stay or Go slow cooker. The district court found that these detailed drawings and descriptions from Hamilton Beach’s meetings, coupled with the communications with its supplier, demonstrated that the invention was ready for patenting.

Hamilton Beach contends that the district court erred in finding that the product that was the subject of the purchase order was ready for patenting because the district court failed to conduct an element-by-element analysis of the precise product that was the subject of the purchase order. Hamilton Beach’s argument is misplaced.

First, the Stay or Go slow cooker is a commercial embodiment of the ’928 patent, a fact that Hamilton Beach does not, and cannot, dispute. And, the Stay or Go slow cooker is the same product that Hamilton Beach both ordered from its foreign supplier and marketed to its retail customers before the critical date. This marketing included presentations that depicted and described the patentable features of the invention, such as the side clips and lid gasket used to keep the lid in place and seal the food inside. The district court found as much.

Hamilton Beach argues, however, that the district court was required to do an element-by-element analysis on the prototypes and product samples on which it was working prior to the critical date. Hamilton Beach contends that such an analysis would show that the samples it marketed, and the specifications upon which it premised its own purchase order, did not meet an important limitation in the asserted claims: that the lid be retained in a “sealing engagement with the container rim

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2 The dissent does not dispute that a firm offer for sale occurred in this case or that the offer for sale was for almost 2000 units of the Stay or Go slow cooker. Instead, it argues that no “commercial” sale occurred because the offer pertained to items that were to be purchased for “experimental use.” No experimental use defense has been asserted by Hamilton Beach in this case, however—neither at the trial court level nor before this court. “Experimental use” is simply not at issue. There is, thus, no threat that this decision will have any impact on that defense; it certainly will not “eviscerate” that defense as the dissent fears. Given the dissent’s citation to *Pfaff*, it appears that the dissent is confusing the concept of experimental use with whether an invention is ready for patenting at the time a sale or offer for sale occurs. …
to inhibit leakage of the food stuffs from the interior of the container.” ‘928 patent, col. 8, ll. 42-44. Hamilton Beach alleges that neither its own engineers nor its supplier were able to perfect a slow cooker that met that limitation until “months” after the critical date.

After review of the district court’s analysis and the facts in this record, we perceive no error in the district court’s conclusion that the product was ready for patenting prior to the critical date. Sunbeam proffered what the district court described as a “veritable tome” of evidence from Hamilton Beach’s meeting with its retail customers that provided specific descriptions of the Stay or Go slow cooker, as well as CAD drawings depicting the Stay or Go, that contained all the limitations of the ’831 and ’928 patents. Under the “ready for patenting” prong, so long as the descriptions and depictions of the slow cooker are sufficiently precise to enable a person of ordinary skill to build the invention, the district court properly concluded that the invention was “ready for patenting.” *Pfaff*, 525 U.S. at 67-68.

The CAD drawings and descriptions from these presentations—containing the same specifications provided to Hamilton Beach’s supplier—are more than enough to enable a person of ordinary skill in the art to practice the claimed invention. Many of the presentations disclosed that the Stay or Go slow cooker used clips and a gasket to hold the lid in place. A person of skill in the art, viewing these presentations, would understand that, if the lid is held in place by a gasket, it would be retained in such a way to prevent food from leaking from the container. Given the relative simplicity of the invention, the descriptions and drawings Hamilton Beach showed to its retail customers and the specifications provided to its supplier are sufficiently enabling and, as an admitted commercial embodiment of the patent-in-suit, would meet every limitation of the asserted claims. No reasonable juror could conclude otherwise.

Aside from the drawings and descriptions, Hamilton Beach also concedes that, by February 2005, it possessed at least one product sample that worked as intended, i.e., the lid sealed in such a way to inhibit food from leaking out of the container. See Oral Argument at 7:15-8:30. The record reveals that, at about the same time as, and prior to the critical date, Hamilton Beach engineers also created a working prototype that was subjected to testing and was successful. In other words, Hamilton Beach possessed working prototypes, or at least one prototype, of the Stay or Go slow cooker, which it concedes met all the limitations of the asserted patent claims. Hamilton Beach’s argument that some of the prototypes did not work as intended is of no moment, moreover, because “fine-tuning” of an invention after the critical date does not mean that the invention was not ready for patenting. *See Weatherchem Corp.*, 163 F.3d at 1332-34. As such, the district court did not err in concluding that the Stay or Go slow cooker was a commercial embodiment of the asserted claims and necessarily met all the claim limitations, and, consequently, concluding that the slow cooker was ready for patenting.

In sum, the district court’s conclusion that there was no genuine dispute of material fact that the patent-in-suit was invalid under § 102(b) was correct. Hamilton Beach received a commercial offer for sale from its foreign supplier, and the patent-
The patented invention was ready for patenting at the time of the sale—as supported by the working prototypes and detailed drawings and descriptions.

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Reyna, Judge, dissenting:

The Supreme Court has instructed that an on-sale bar under 35 U.S.C. § 102(b) shall arise, if at all, only when the patented invention is the subject of a commercial offer for sale and the invention is ready for patenting more than one year before the patent’s filing date. *Pfaff v. Wells Elecs.*, 525 U.S. 55, 67 (1998). Yet the majority concludes that Hamilton Beach’s purchase order sent to its foreign supplier, which asked the supplier to build a set of slow cookers pursuant to Hamilton Beach’s specifications, resulted in an offer to sell a patented invention that anticipates the claims of Hamilton Beach’s patent. In order to reach this conclusion, the majority is quick to note that there is no “supplier exception” to otherwise anticipatory offers for sale under § 102(b), while at the same time it overlooks the Supreme Court’s requirement that the offer be a “commercial” one. Because the majority’s oversight portends grave consequences for innovation and experimental use, I respectfully dissent.

When the Supreme Court decided *Pfaff*, it explicitly rejected this court’s multifactor, “totality of the circumstances” test we had previously used to determine whether there was an on-sale bar. 525 U.S. at 66 & n.11. In its place, the Court substituted a two-pronged test, having a first prong that requires a commercial offer for sale. Id. at 67. This requirement makes sense: “An inventor can both understand and control the timing of the first commercial marketing of his invention.” *Id.*

Indeed, the Court was careful to distinguish between a “sale [that] was commercial rather than experimental in character.” *Id.* In my view, an overly-broad application of the no-supplier-exception rule would all but abolish this distinction and render the experimental-use exception useless for a significant class of innovators.

After *Pfaff* was decided, this court began fashioning the no-supplier-exception rule in *Brasseler*. The patentee, Brasseler, U.S.A., had its exclusive manufacturer produce 3,000 surgical saws embodying the invention set forth in its patent’s claims. Noting that the saws were ordered “in large quantity for resale,” this court concluded that “[t]he transaction at issue undisputedly was a ‘sale’ in a commercial law sense.” *Id.* Indeed, it was “not a case in which an individual inventor takes a design to a fabricator and pays the fabricator for its services in fabricating a few sample products. *** [Instead, the manufacturer] made a large number of the agreed-upon product for general marketing by Brasseler.” Only after concluding that the sale was commercial in nature did this court reject the assertion that the relationship between the supplier and the patentee somehow prevented the sale from triggering the on-sale bar.

Shortly thereafter, in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), this court applied the no-supplier-exception after concluding that the offer was commercial in nature. The patentee, OEA, Inc., contracted with its supplier to provide it with 20,000 patented embodiments of its “all-glass header” for use in automobile airbags. In addition, the patentee agreed to supply the supplier with millions of the patented headers annually. Unsurprisingly, OEA “conceded that
these transactions were ‘commercial,’ not experimental” given that it was unrebutted that OEA “had purchased [the headers] for commercial purposes.” Thus, the only two instances where this court has deployed the no-supplier-exception rule involved offers or sales that unquestionably met the Supreme Court’s requirement that the offer be part of a “commercial” offer or sale.

With no review of whether the offer was commercial in nature, the majority in this case has extended the no-supplier-exception rule to a case without considering whether the purchase order was placed for purely experimental purposes. Yet the circumstances indicate that it was. The purchase order “was not the result of customer demand or projections,” and, at the time the order was placed, Hamilton Beach was repeatedly changing the product specification due to a series of design failures, most notably, foodstuffs leaking through the lid. The design remained unstable for nearly three months after the purchase order was placed. Just as the Supreme Court applied the experimental-use exception when Mr. Nicholson, the patentee in City of Elizabeth, tested and perfected his pavement on a busy toll road in Boston—inspecting and tapping it with his cane almost daily—for more than six years before filing for a patent, 97 U.S. at 133-37, Hamilton Beach was similarly entitled to test and perfect its slow cooker under the experimental-use exception. See Pfaff, 525 U.S. at 64 (“[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye.”).

My greatest concerns involve the implications this case will have for future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities. Whenever the development process requires those entities to manufacture working prototypes or pre-mass-production samples,

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2 The majority states that the “experimental use defense has [not] been asserted by Hamilton Beach in this case.” While Hamilton Beach did not use the phrase “experimental use,” it argued at length that its offer for sale was non-commercial and that its engineers were attempting to overcome serious shortcomings when the offer was made. The majority chooses to ignore the interplay between the requirement for a commercial offer for sale and experimental use. I find that the issues addressed by the parties and, indeed the majority, lay a sufficient framework under which to analyze all the issues in this case.

3 The majority contends that the use intended by Hamilton Beach in this case was not experimental because it ordered almost 2,000 (actually 1,952) slow cookers. This sort of quantitative analysis was previously accepted under the “totality of the circumstances” test—a test rejected by the Supreme Court in Pfaff. Here, Hamilton Beach was not “stockpiling] commercial embodiments of their patented invention” as was occurring in Brasseler and Special Devices. Special Devices, 270 F.3d at 1354. It would make no sense for Hamilton Beach to stockpile slow cookers for future sales when its slow cookers were leaking at the time. Rather, the circumstances suggest that Hamilton Beach was in the midst of testing and perfecting its slow cookers under the experimental use exception when the offer was made. This is true—and can be true—even if the invention was ready for patenting at that time.
they often have no choice but to reach out to third-party suppliers. Under the majority’s holding in this case, a single offer to buy for purely experimental purposes may trigger the on-sale bar, and the experimental-use exception will offer them no salvation. It is from this evisceration of the experimental-use exception that I respectfully dissent.

Steven C. Carlson & Leeron G. Kalay,
Old World Fix for a New Patent Problem?,
IP Law & Business, Apr/May 2009

Outsourcing the synthesis of chemical compounds is a growing practice in the pharmaceutical industry. Increasingly, drug researchers order novel compounds from third-party vendors, then subject them to many rounds of study. Years may pass before a patent application is filed on a particular compound.

A potential problem with this approach lies in patent law’s “on-sale bar,” which prohibits filing patents on inventions more than one year after they are ready for patenting and subject to a commercial offer for sale. Although the sale of newly synthesized compounds from outsourcers back to pharmaceutical companies may adhere to underlying policies and objectives in patent law, it may still qualify as a barring event. The nineteenth-century doctrine of bailment may provide a solution. Historically applied to the creation of such goods as wine and cheese, this common-law structure has been revived, including in the life sciences field.

Under the Uniform Commercial Code, a sale occurs only where title passes to a buyer. A bailment by definition is not a sale because it allows for the transfer of goods without the passing of title. A bailment requires the creation of a trust, in which a bailor authorizes the recipient to hold, and if need be to modify, the object of that trust—leaving your car at the garage for repairs, for example. …

B.A. Ballou & Co. v. Citytrust
591 A.2d 126 (Conn. 1991)

Covello, Justice:

This is an action in conversion. The plaintiff, B.A. Ballou & Co., alleges that the defendant, Citytrust, wrongfully appropriated the plaintiff’s scrap metal while it was in the possession of a third party, Bridgeport Rolling Mills Company. The issues on appeal are: (1) who has the burden of proving whether a bailment exists; [and] (2) whether under the circumstances presented a bailment existed … . We conclude that (1) the burden of proving a bailment lies with the party whose claim to ownership relies upon such a relationship, and (2) no bailment existed here.

The parties stipulated as follows: the plaintiff Ballou manufactures jewelry. Bridgeport Rolling Mills, Inc. (Brimco), was a metal fabricator. Brimco supplied Ballou with sheets of stock brass, an alloy that Ballou used to manufacture jewelry. Ballou shipped its leftover brass back to Brimco, which commingled it with scrap brass received from other companies. Brimco then shipped the accumulated scrap to
a processing mill, which added new base metal as required and reconstituted it into finished brass that Brimco thereafter kept in its inventory available for subsequent orders. The type of brass needed by a given customer varied from time to time and therefore the new brass returned to the customer by Brimco could have an entirely different composition than the scrap sent by the customer. For example, Brimco might receive brass scrap composed of 70% copper and 30% zinc and return brass composed of 85% copper and 15% zinc. The only record of the brass sent by Ballou to Brimco was a “toll metal account” that listed the weight of each base metal in a given customer’s account. Because Brimco commingled the scrap metal and had it remanufactured by a third party who mixed it with new metal as needed, there was no way of determining whether any of the same scrap sent to Brimco by Ballou ever returned to Ballou as finished brass.

On May 22, 1981, Brimco entered into a security agreement with the defendant Citytrust for a revolving line of credit. The loan was secured by an interest in “[a]ll inventory of the Borrower, now owned or hereafter acquired. *** All goods *** or other property *** in which Borrower has an interest *** or come[s] into possession.” Unknown to Ballou, Brimco consistently represented to Citytrust that it owned all the scrap metal in its possession. In June, 1987, Citytrust, as a secured creditor, took possession of Brimco’s assets pursuant to the security agreement, including all metal on site.

Ballou thereafter brought an action against Citytrust for its alleged conversion of Ballou’s scrap metal and for violation of the Connecticut Unfair Trade Practices Act. The trial court concluded that Ballou had retained title to the scrap and that a bailment therefore existed. It accordingly rendered judgment for Ballou in the amount of $114,575. Citytrust appealed, claiming that the trial court (1) incorrectly concluded that a bailment existed [and] (2) improperly shifted the burden of proof to Citytrust to prove that a bailment did not exist … .

Citytrust first claims that the trial court improperly placed the burden of proving a necessary element of Ballou’s case upon Citytrust. In order for Ballou to prevail on its conversion claim, it must demonstrate that it continued to own the scrap. Gilbert v. Walker, 64 Conn. 390, 394 (1890). Since Brimco had possession, Ballou was required to prove the existence of a bailment. It is an “elementary rule that whenever the existence of any fact is necessary in order that a party may make out his case *** the burden is on such party to show the existence of such fact.” Nikitiuk v. Pishney, 153 Conn. 545, 552 (1966); Eichman v. J & J Building Co., 216 Conn. 443, 451 (1990). This rule holds true for bailment cases as well. See Wells v. Active Automobile Exchange, Inc., 99 Conn. 523, 527 (1923). While the trial court arguably assigned the burden of proof of this issue to Citytrust we need not take up Citytrust’s claim in this regard because we find that, under the facts as stipulated, a bailment could not have existed.

Ballou claims that the toll metal account between itself and Brimco constituted a bailment. Ballou argues that, as a bailor, it retained title to the scrap metal in Brimco’s possession and that Citytrust therefore became liable to it in conversion for seizing its scrap.
A bailment “involves a delivery of the thing bailed into the possession of the bailee, under a contract to return it to the owner according to the terms of the agreement.” Seedman v. Jaffer, 104 Conn. 222, 226 (1926), quoting Murray v. Paramount Petroleum & Products Co., 101 Conn. 238, 242 (1924). “A relationship of bailor-bailee arises when the owner, while retaining general title, delivers personal property to another for some particular purpose upon an express or implied contract to redeliver the goods when the purpose has been fulfilled, or to otherwise deal with the goods according to the bailor’s directions.” Maulding v. United States, 257 F.2d 56, 60 (9th Cir. 1958). “In bailment, the owner or bailor has a general property [interest] in the goods bailed *** .” McKesson & Robbins, Inc. v. Walsh, 132 Conn. 158, 162 (1945). The bailee, on the other hand, has mere possession of items left in its care pursuant to the bailment. Sturm v. Boker, 150 U.S. 312, 330 (1893).[†]

The trial court found that scrap from Ballou had been commingled with scrap from other sources and concluded that “[t]he fact that the property of the plaintiff is commingled with like property of another *** does not necessarily force the conclusion that the transaction is not a bailment.” We agree that the commingling of fun-

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2 According to Blackstone, and others, a bailment “is a delivery of goods in trust, upon a contract, expressed or implied, that the trust shall be faithfully executed on the part of the bailee.” 2 Blackstone’s Commentaries 452; see I. Edwards, A Treatise on the Law of Bailments 33; Black’s Law Dictionary (4th Ed.). At one time we also adhered to this definition. Zetserstrom v. Thomas, 92 Conn. 702, 704 (1918); Samelson v. Harper’s Furs, Inc., 20 Conn. Sup. 37, 39 (1955), aff’d, 144 Conn. 368 (1957). In a trust, however, the trustee has legal title to the res of the trust. G. Bogert, Trusts § 1 (5th ed.). In a bailment, on the other hand, the bailee does not have legal title to the thing bailed, but mere possession. Sturm v. Boker, 150 U.S. 312, 330 (1893); McKesson & Robbins, Inc. v. Walsh, 132 Conn. 158, 162 (1945). We prefer, therefore, the definition established in Seedman v. Jaffer, 104 Conn. 222, 226 (1926). See generally 1 Restatement 2d of Trusts § 5; A. Dobie, Handbook on the Law of Bailments & Carriers § 1.

† [ Ed. Note — In Sturm, a pre-Erie bailment case, the Supreme Court stated as follows: “The recognized distinction between bailment and sale is that when the identical article is to be returned in the same or in some altered form, the contract is one of bailment, and the title to the property is not changed. On the other hand, when there is no obligation to return the specific article, and the receiver is at liberty to return another thing of value, he becomes a debtor to make the return, and the title to the property is changed; the transaction is a sale.” 150 U.S. at 329-30 (emphasis added). ]

3 The trial court relied primarily upon Public Service Electric & Gas Co. v. FPC, 371 F.2d 1 (3d Cir. 1967). In PSE&G, a company arranged to have gas transported through a pipeline. The court found that a bailment existed even though the company was by no means entitled to have the identical gas delivered back to it. Id. at 4. Because the gas was only transported, and not altered in any form, that case is distinguishable from the type of bailment alleged here.
gible goods alone does not defeat a bailment when the bailor specifically intended to retain ownership of a known share of the commingled goods. Public Service Electric & Gas Co. v. FPC, 371 F.2d 1 (3d Cir. 1967); Slaughter v. Green, 22 Va. 3, 9 (1821).

A different rule, however, applies where the purpose of the bailment is to alter or remanufacture goods surrendered to the alleged bailee. The bailment in such an instance is termed “a bailment *** locatio operis faciendi [i.e.] a bailment where work and labor *** are to be performed upon the thing delivered to the bailee. The parties to a bailment of this character—one for their mutual benefit—enter into a contract, express or implied, or both, by which the bailee engages to perform the agreed services and return the thing bailed in its altered *** form, and the bailor in return for the services of the bailee agrees to pay him the agreed-upon compensation.” Douglass v. Hart, 103 Conn. 685, 688 (1925).

In a bailment of this type, “the question of [whether a transaction constitutes a] bailment or not is determined by whether the identical article delivered to the manufacturer is to be returned to the party making the advance. Thus, where logs are delivered to be sawed into boards, or leather to be made into shoes, rags into paper, olives into oil, grapes into wine, wheat into flour, if the product of the identical articles delivered is to be returned to the original owner in a new form, it is said to be a bailment, and the title never vests in the manufacturer. If, on the other hand, the manufacturer is not bound to return the same wheat or flour or paper, but may deliver any other of equal value, it is said [not to be a bailment] ***.” Powder Co. v. Burkhardt, 97 U.S. 110, 116 (1877) (emphasis added); see Clark v. Rosen, 126 Conn. 707, 708-10 (1940); Douglass v. Hart, 103 Conn. at 687-88; Johnson v. Allen, 70 Conn. 738, 744-45 (1898).

The trial court also cited In re Sitkin Smelting & Refining, 639 F.2d 1216 (5th Cir. 1981). In Sitkin, the court found that a bailment existed when Kodak delivered film waste to Sitkin for waste processing and to extract the silver. Id. at 1217. The court emphasized the facts that: (1) Sitkin did not carry the film as inventory; (2) the film was clearly imprinted with Kodak’s name; and (3) the film was stored in its original cartons and kept separate from other products. Id. Sitkin, therefore, is distinguishable from the present case because there was no evidence of commingling.

The trial court also relied upon General Motors Corp. v. Bristol, 690 F.2d 26, 30-31 (2d Cir. 1982), in which Judge Mansfield, in a concurring opinion, found that a bailment existed when GM shipped scrap metal to a manufacturer for processing into alloy strips under a “tolling arrangement.” In Bristol, however, the written agreement clearly stated that GM retained title to the scrap in the manufacturer’s possession until it was remanufactured into alloy. Id. at 27. In addition, the bailee was required to return the identical scrap to GM if not processed into alloy strips. Judge Mansfield, concurring in Bristol, stated that a bailment may exist when goods are commingled and remanufactured. As support for this statement, however, he cites PSE&G and 8 Am. Jur. 2d, Bailments § 51. As noted above, PSE&G stands only for the proposition that commingling alone does not defeat a bailment.
In order for the instant transaction to constitute a bailment, therefore, it is necessary that the final product be composed of the identical property originally delivered. The trial court found that the scrap was commingled, that the brass returned to Ballou need not have been of the same type of alloy and that “there was no understanding or agreement that the precise thing bailed would be returned to the plaintiff.” The trial court further found that if any of the original scrap metal found its way back to Ballou, “this would be solely by chance.” Because there was no evidence that the property returned was the product of the property delivered, except “solely by chance,” we conclude that the arrangement between Ballou and Brimco could not constitute a bailment.

The judgment of the trial court is reversed and the matter is remanded with direction to render judgment for the defendant.

**Metallizing Eng’g v. Kenyon Bearing & Auto Parts**

153 F.2d 516 (2d Cir. 1946)

*L. Hand, Judge:*

The defendants appeal from the usual decree holding valid and infringed all but three of the claims of a reissued patent, issued to the plaintiff’s assignor, Meduna; the original patent issued on May 25, 1943, upon an application filed on August 6, 1942. The patent is for the process of “so conditioning a metal surface that the same is, as a rule, capable of bonding thereto applied spray metal to a higher degree than is normally procurable with hitherto known practices.” It is primarily useful for building up the worn metal parts of a machine. The art had for many years done this by what the patent calls “spray metal,” which means metal sprayed in molten form upon the surface which it is desired to build up. This process is called “metalizing,” and it had been known for nearly thirty years before Meduna’s invention; but about fifteen or twenty years ago it was found that, to secure a satisfactory bond between the “spray metal” and the surface, the surface must be roughened so that there would be fine undercut areas in it upon which the sprayed surface could take hold; and of course the surface must itself be clean. …

…

4 A change in the character or nature of personality can affect a right of ownership. Under the doctrine of accession, if the labor of one person is combined with material belonging to another, the owner of the original raw material can retain title to, and ownership of, the finished product. *Atlas Ins. Co. v. Gibbs*, 121 Conn. 188, 192-93 (1936); *Mather v. Chapman*, 40 Conn. 382, 397 (1873). If, however, the identity of the item has been destroyed, its nature substantially changed, or value greatly enhanced, as between the manufacturer and the original owner, the owner loses his right of ownership and retains only an action for the value of the goods lost. *Atlas Ins. Co. v. Gibbs*, 121 Conn. at 192-93. Similarly, in a bailment *locatio operis faciendi*, changes in the nature of the property bailed have the potential to affect the property interest of the bailor. The law of bailments has responded, in a manner similar to the law of property, by finding that a bailment will still exist if, as noted above, the identity of the item has not been destroyed.
The only question which we find necessary to decide is as to Meduna's public use of the patented process more than one year before August 6, 1942. The district judge made findings about this, which are supported by the testimony and which we accept. ... The kernel of them is the following: "the inventor's main purpose in his use of the process prior to August 6, 1941, and especially in respect to all jobs for owners not known to him, was commercial, and *** an experimental purpose in connection with such use was subordinate only." Upon this finding he concluded as matter of law that, since the use before the critical date—August 6, 1941—was not primarily for the purposes of experiment, the use was not excused for that reason. Smith & Griggs Manufacturing Co. v. Sprague, 123 U.S. 249, 256; Aerovox Corp. v. Polymet Manufacturing Corp., 2 Cir., 67 F.2d 860, 862. Moreover, he also concluded that the use was not public but secret, and for that reason that its predominantly commercial character did prevent it from invalidating the patent. For the last he relied upon our decisions in Peerless Roll Leaf Co. v. Griffin & Sons, 29 F.2d 646, and Gillman v. Stern, 114 F.2d 28. We think that his analysis of Peerless Roll Leaf Co. v. Griffin & Sons was altogether correct, and that he had no alternative but to follow that decision; on the other hand, we now think that we were then wrong and that the decision must be overruled for reasons we shall state. Gillman v. Stern, was, however, rightly decided.

Section one of the first and second Patent Acts, 1 Stat. 109 and 318, declared that the petition for a patent must state that the subject matter had not been "before known or used." Section six of the Act of 1836, 5 Stat. 117, changed this by providing in addition that the invention must not at the time of the application for a patent have been "in public use or on sale" with the inventor's "consent or allowance"; and § 7 of the Act of 1839, 5 Stat. 353, provided that "no patent shall be held to be invalid by reason of such purchase, sale, or use prior to the application for a patent *** except on proof of abandonment of such invention to the public; or that such purchase, sale, or prior use has been for more than two years prior to such application ***." Section 4886 of the Revised Statutes made it a condition upon patentability that the invention shall not have been "in public use or on sale for more than two years prior to his application," and that it shall not have been "proved to have been abandoned." This is in substance the same as the Act of 1839, and is precisely the same as § 31 of Title 35, U.S.C., except that the prior use is now limited to the United States, and to one year before the application.

So far as we can find, the first case which dealt with the effect of prior use by the patentee was Pennock v. Dialogue, 2 Pet. 1, 4, in which the invention had been completed in 1811, and the patent granted in 1818 for a process of making hose by which the sections were joined together in such a way that the joints resisted pressure as well as the other parts [did]. It did not appear that the joints in any way disclosed the process; but the patentee, between the discovery of the invention and the grant of the patent, had sold 13,000 feet of hose; and as to this the judge charged: "If the public, with the knowledge and tacit consent of the inventor, be permitted to use the invention, without opposition, it is a fraud on the public afterwards to take out a patent." The Supreme Court affirmed a judgment for the defendant, on the ground that the invention had been "known or used before the ap-
application.” “If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should *** make and sell his invention publicly, and thus gather the whole profits, *** it would materially retard the progress of science and the useful arts” to allow him fourteen years of legal monopoly “when the danger of competition should force him to secure the exclusive right” 2 Pet. at page 19. In Shaw v. Cooper, 7 Pet. 292, the public use was not by the inventor, but he had neglected to prevent it after he had learned of it, and this defeated the patent. “Whatever may be the intention of the inventor, if he suffers his invention to go into public use, through any means whatsoever, without an immediate assertion of his right, he is not entitled to a patent” 7 Pet. at page 323. In Kendall v. Winsor, 21 How. 322, the inventor had kept the machine secret, but had sold the harness which it produced, so that the facts presented the same situation as here. Since the jury brought in a verdict for the defendant on the issue of abandonment, the case adds nothing except for the dicta on page 328 of 21 How., 16 L.Ed. 165: “the inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public, comes not with in the policy or objects of the Constitution or acts of Congress.” In Egbert v. Lippmann, 104 U.S. 333, although the patent was for the product which was sold, nothing could be learned about it without taking it apart, yet it was a public use within the statute. In Hall v. Macneale, 107 U.S. 90, the situation was the same.

In the lower courts we may begin with the often cited decision in Macbeth-Evans Glass Co. v. General Electric Co., 6 Cir., 246 F. 695, which concerned a process patent for making illuminating glass. The patentee had kept the process as secret as possible, but for ten years had sold the glass, although this did not, so far as appears, disclose the process. The court held the patent invalid for two reasons, as we understand them: the first was that the delay either indicated an intention to abandon, or was of itself a forfeiture, because of the inconsistency of a practical monopoly by means of secrecy and of a later legal monopoly by means of a patent. So far, it was not an interpretation of “prior use” in the statute; but, beginning on page 702 of 246 F. 695, Judge Warrington seems to have been construing that phrase and to hold that the sales were such a use. In Allinson Manufacturing Co. v. Ideal Filter Co., 8 Cir., 21 F.2d 22, the patent was for a machine for purifying gasoline: the machine was kept secret, but the gasoline had been sold for a period of six years before the application was filed. As in Macbeth-Evans Glass Co. v. General Electric Co., the [Allinson] court apparently invalidated the patent on two grounds: one was that the inventor had abandoned the right to a patent, or had forfeited it by his long delay. We are disposed however to read the latter part—pages 27 and 28 of 21 F.2d—as holding that the sale of gasoline was a “prior use” of the machine, notwithstanding its concealment. ...

Coming now to our own decisions (the opinions in all of which I wrote), the first was Grasselli Chemical Co. v. National Aniline & Chemical Co., 2 Cir., 26 F.2d 305, in which the patent was for a process which had been kept secret, but the product had been sold upon the market for more than two years. We held that, although the process could not have been discovered from the product, the sales constituted a “prior use,” relying upon Egbert v. Lippmann, 104 U.S. 333, and Hall v.
Macneale, 107 U.S. 90. There was nothing in this inconsistent with what we are now holding. But in Peerless Roll Leaf Co. v. Griffin & Sons, 2 Cir., 29 F.2d 646, where the patent was for a machine, which had been kept secret, but whose output had been freely sold on the market, we sustained the patent on the ground that “the sale of the product was irrelevant, since no knowledge could possibly be acquired of the machine in that way. In this respect the machine differs from a process *** or from any other invention necessarily contained in a product.” 29 F.2d at 649. So far as we can now find, there is nothing to support this distinction in the authorities, and we shall try to show that we misapprehended the theory on which the prior use by an inventor forfeits his right to a patent. In Aerovox Corp. v. Polymet Mfg., 2 Cir., 67 F.2d 860, the patent was also for a process, the use of which we held not to have been experimental, though not secret. Thus our decision sustaining the patent was right; but apparently we were by implication reverting to the doctrine of the Peerless case when we added that it was doubtful whether the process could be detected from the product .... In Gillman v. Stern, 2 Cir., 114 F.2d 28, it was not the inventor, but a third person who used the machine secretly and sold the product openly, and there was therefore no question either of abandonment or forfeiture by the inventor. The only issue was whether a prior use which did not disclose the invention to the art was within the statute; and it is well settled that it is not. As in the case of any other anticipation, the issue of invention must then be determined by how much the inventor has contributed any new information to the art. Gayler v. Wilder, 10 How. 477, 496, 497; Tilghman v. Proctor, 102 U.S. 707, 711.

From the foregoing it appears that in Peerless Roll Leaf Co. v. Griffin & Sons, we confused two separate doctrines: (1) The effect upon his right to a patent of the inventor’s competitive exploitation of his machine or of his process; (2) the contribution which a prior use by another person makes to the art. Both do indeed come within the phrase, “prior use”; but the first is a defence for quite different reasons from the second. It had its origin—at least in this country—in the passage we have quoted from Pennock v. Dialogue, i.e., that it is a condition upon an inventor’s right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly. It is true that for the limited period of two years he was allowed to do so, possibly in order to give him time to prepare an application; and even that has been recently cut down by half. But if he goes beyond that period of probation, he forfeits his right regardless of how little the public may have learned about the invention; just as he can forfeit it by too long concealment, even without exploiting the invention at all. Such a forfeiture has nothing to do with abandonment, which presupposes a deliberate, though not necessarily an express, surrender of any right to a patent. Although the evidence of both may at times overlap, each comes from a quite different legal source: one, from the fact that by renouncing the right the inventor irrevocably surrenders it; the other, from the fiat of Congress that it is part of the consideration for a patent that the public shall as soon as possible begin to enjoy the disclosure.

It is indeed true that an inventor may continue for more than a year to practice his invention for his private purposes or his own enjoyment and later patent it. But that is, properly considered, not an exception to the doctrine, for he is not then
making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his monopoly. Besides, as we have seen, even that privilege has its limits, for he may conceal it so long that he will lose his right to a patent even though he does not use it at all. With that question we have not however any concern here.

Judgment reversed; complaint dismissed.

**D.L. Auld Co. v. Chroma Graphics Corp.**

714 F.2d 1144 (Fed. Cir. 1983)

*Markey, Chief Judge:*

...  
On October 15, 1981, the D.L. Auld Company (Auld) sued Chroma Graphics Corp. (Chroma) in the Eastern District of Tennessee for infringement of Patent No. 4,100,010 (the Waugh patent) issued on a continuing application filed July 2, 1976 of an original application filed June 12, 1974. The patent claims are drawn to a method of forming foil-backed inserts in the form of cast decorative emblems.

...  
Chroma took a discovery deposition of the inventor, Robert E. Waugh, who was also Vice President for Research and Development of Auld, the assignee of the patent. Submitting portions of that deposition and documents from Auld’s files, Chroma moved for summary judgment on the ground that the invention had been “on sale” for more than one year before June 12, 1974.

...  
On October 22, 1982, the magistrate entered an order granting the motion, accompanied by a memorandum opinion.

...  
Waugh’s invention is a method. The parties cite numerous cases involving “on sale” considerations in respect of product inventions under 35 U.S.C. § 102(b). The focus of inquiry here, however, is on the method. If Auld produced an emblem by the method of the invention and offered that emblem for sale before the critical date, the right to a patent on the method must be declared forfeited. *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2nd Cir. 1946). The “forfeiture” theory expressed in *Metallizing* parallels the statutory scheme of 35 U.S.C. § 102(b), the intent of which is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed. The record includes testimonial and documentary evidence establishing that the claimed method was employed in preparing a number of sample emblems and that Auld attempted to profit from use of that method by offering some of those samples for sale to a number of potential buyers well before the critical date. Those facts operate to create a forfeiture of any right to the grant of a valid patent on the method to Auld.

Where a method is kept secret, and remains secret after a sale of the product of the method, that sale will not, of course, bar another inventor from the grant of a patent on that method. The situation is different where, as here, that sale is made by
the applicant for patent or his assignee. Though the magistrate referred to § 102(b), he did so in recognizing that the “activity” of Auld here was that which the statute “attempts to limit to one year.” In so doing, the magistrate correctly applied the concept explicated in Metallizing, i.e., that a party’s placing of the product of a method invention on sale more than a year before that party’s application filing date must act as a forfeiture of any right to the grant of a valid patent on the method to that party if circumvention of the policy animating § 102(b) is to be avoided in respect of patents on method inventions.

…

The involved emblems include a layer of clear plastic having a curved outer surface formed on a decoration-bearing base. Since 1965, Auld sold that type of emblem to the auto industry. The early emblems were made by the “Vitrolux” method, in which the base is a shallow cavity designed to receive a measured amount of liquid plastic, while the base was held horizontal. The quantity of plastic was greater than that required to fill the cavity, producing a curved upper surface. The plastic did not overflow the cavity walls because of its surface tension.

In about 1968, Waugh began work on a variation of the Vitrolux process. That work resulted in the Vitrofoil method, the subject of patent 4,100,010. The Vitrofoil method employs a flat sheet of metal as the base on which a metered amount of liquid plastic is deposited while the base is held horizontal. The plastic flows to the edge of the sheet without overflowing; its surface tension causing it to stop at the sheet’s edge to form a curved upper surface.

Waugh testified in his deposition that as early as 1969, Auld was producing samples in accordance with the claimed method by hand, and that between 1969 and June 1973, Auld “showed these samples to people and said we [Auld] could do this, and we [Auld] could not generate any interest for the product.” Attempts to market those emblems were conducted by an outside manufacturer’s representative and Auld’s sales staff. The emblem produced by the Vitrofoil method initially would not sell and Auld for a period “shelved” the emblem produced by the Vitrofoil method.

Sample emblems were submitted to prospective customers, such as Cadillac, General Motors, Buick, Ford, Chrysler, and the National Hockey League and the National Football League, through a company called International Crest. Waugh said that the established sales practice in the automotive industry was to present samples to prospective customers, that Auld would not “tool up” without a purchase order, and that the submission of sample emblems produced by the Vitrofoil method followed Auld’s established sales procedure.

Waugh testified that sample emblems submitted to prospective customers before the critical date were made in the laboratory following each of the steps set forth in Claim 1 of the patent in suit. He further said that the claimed method was not followed on some samples and a “postforming” operation was required on those particular emblems because they curled.

Waugh testified that of the samples submitted before June 1973 by the Auld sales department to International Crest, to interest them in the product for the
National Football and Hockey Leagues, some were not made by the claimed method, but that others were. Auld quoted pricing and delivery dates in writing, for an order of more than 150,000 emblems, to International Crest.

Thus the record evidence includes corporate documents and testimony establishing that some sample emblems were produced by hand, following the steps of the method, and that those hand-produced emblems were offered for sale before June 12, 1973. Against that evidence, Auld makes numerous arguments and assertions respecting other samples and other parts of the record, insisting that there are conflicts in testimony improperly resolved on a motion for summary judgment. On careful review of each such argument and assertion and after viewing all evidence and inferences in a light most favorable to Auld, we are convinced that no material conflicts or credibility questions were or needed to be resolved by the magistrate and that no issue of material fact requiring a trial to resolve is present on this record.

... Auld admits that emblems were made between 1969 and 1972 and that at least one was supplied, with prices quoted, to International Crest in “late 1972—early 1973.” It says, however, that those emblems were made by a “laboratory” method; that a material issue exists on whether the offers fell within the “experimental” exception to the “on sale” bar of 35 U.S.C. § 102(b); that whether the offers were for experimental purposes is a matter of Auld’s intent and thus ill-suited to resolution by summary judgment; that the magistrate improperly shifted the burden of proof by requiring Auld to show that the offer for sale was for experimental purposes; that no sale was made to International Crest; that some samples were not made by the claimed method; that it was error to grant summary judgment without receiving the proffered testimony of Auld salesmen; that the claimed method was for a manufacturing process involving a series of emblems, while in the “laboratory” method emblems were made one by one and that method was not demonstrated to be practical or readily reproducible; that affidavits of Waugh, Tanner, and David Auld, filed to correct and clarify “ambiguities and inconsistencies” in Waugh’s deposition, raise a material issue on whether the claimed method had been reduced to practice before June, 1973; and that those affidavits show that emblems provided Chrysler were not made by the patented method because they were not made in a manufacturing process involving a series of emblems, were not held flat, and had to be postformed.

Labeling the method employed in making the sample for International Crest as a “laboratory” method raises no material fact issue. The method was that of Claim 1 and was successfully performed to produce an emblem offered for sale, or resale, by International Crest. That is all the law requires. *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928); *Breen v. Miller*, 347 F.2d 623 (CCPA 1965). Waugh’s testimony establishes unequivocally that the “laboratory” method involved each step of the claimed method, and that each such step was performed in producing some early samples for International Crest. When carefully read, the “clarifying” affidavits do not contradict those facts. Portions of those affidavits quoted by Auld relate to different samples, to portions of the patent specification (not the claims), to commercial production, and to other customers. Even then, the only asserted differences between the patented method and the “laboratory” meth-
od are the use of adhesive and holding the foil shapes flat. Waugh’s testimony was unequivocal that those very steps were employed in making some samples by the “laboratory” method, and nothing in the affidavits contradicts that testimony.

Auld’s attempt to establish a material issue of fact respecting the “experimental” exception to 35 U.S.C. § 102(b) is misdirected. First, each of Auld’s citations to evidence in the record relates to later experimentation on mass production by machine for commercialization in quantity, not to any experimentation on the earlier performed method itself. Second, Auld’s reliance on the labeling of the sample emblems as “lab samples” submitted to customers for “evaluation” is irrelevant. The claim is for a method, not a product. That the method would produce the product was known. Submission of the emblems for sale if the customer liked them is not experimentation on the method.

Similarly, Auld’s reliance on intent of the patent holder must fail. Mr. David Auld said International Crest was told that the samples were experimental. As above indicated, however, the question is whether the method had been successfully performed in making the samples, not whether the samples were themselves “experimental.” The record establishes that the claimed method was successfully performed, albeit by hand, that it produced an emblem, and that the emblem was offered for sale. The corporate documents of Auld make plain its intent to sell the emblems produced by the “laboratory” method, which is the same as the claimed method. That Auld might have to tool up for mass production if a customer gave a large order bears no relation to whether experimentation was required on the claimed method itself. Moreover, if a mere allegation of experimental intent were sufficient, there would rarely if ever be room for summary judgment based on a true “on sale” defense under 35 U.S.C. § 102(b).

Nor did the magistrate effectively shift the burden to Auld on the experimentation issue. Once evidence that an invention was on sale or, as here, that the product of a method invention was on sale, is presented, countervailing evidence establishing an experimental purpose must necessarily come from the patentee. To defeat a motion for summary judgment, a patentee need not prove an experimental purpose, but must submit facts indicating an ability to come forward with evidence that such proof is possible. … Chroma having established a prima facie case, it fell to Auld to submit evidence, by affidavit or otherwise, setting forth specific facts raising a genuine issue for trial. First National Bank of Arizona v. Cities Service Co., 391 U.S. 253 (1968).

Nothing in the submissions of Auld to the magistrate indicated any possibility that the performance by hand of the method in producing some of the International Crest samples was itself in any manner experimental. As above indicated, that Auld may have experimented, after the critical date, with means to achieve tooling for mass production bears no relation to whether the method of the claim had earlier been used and the product of that earlier use offered for sale.

That no sale was actually made to International Crest is irrelevant. An offer to sell is sufficient under the policy animating the statute, which proscribes not a sale, but a placing “on sale.” 35 U.S.C. § 102(b); General Electric Co. v. U.S., 654 F.2d 55 (Ct. Cl. 1981).
Similarly, submission of evidence that some samples offered for sale were not made by the claimed method cannot raise a material issue of fact, and thus preclude summary judgment, in the face of uncontradicted evidence that other samples had been made by the claimed method and offered for sale before the critical date.

...  

In a further effort to distinguish what it calls its “laboratory” method from the claimed method, Auld says the Waugh patent is limited to “a manufacturing process, involving a series of foil shapes.” Its difficulty here is twofold. First, the claim is for “[a] method of forming foil backed inserts.” It is not for a method of manufacturing or mass producing inserts, and the word “series” does not make it such. Second, Waugh testified unequivocally that a series of foil shapes were produced by hand (the “laboratory” method), following each step of the claimed method. If the “laboratory” method did involve the making of emblems one-by-one, that fact would merely mean a greater time interval between individual emblems in a series. There is nothing of record to indicate that the “laboratory” method was itself impractical or not readily reproducible as a method.

The affidavits filed in an effort to “clarify” Waugh’s deposition fail to contradict his crucial testimony that every step of the claimed method was followed in producing emblems offered to International Crest. The Wanner and David Auld affidavits assert that the claimed method was “not reduced to practice” until August, 1973. Not only is that assertion a legal conclusion, it relates to the manufacturing of an order for Chrysler, and does not contradict Waugh’s testimony establishing reduction to practice of the claimed method to produce the samples offered earlier to International Crest. Waugh’s affidavit, being similarly directed to other samples and to a method “as performed in May 1973,” does not contradict his unequivocal testimony that every step of the claimed method was successfully performed earlier in producing emblems offered to International Crest.

The effort here to staunch the fatal wound inflicted upon Auld’s suit by Waugh’s deposition testimony is not new to the law. In International Harvester Co. v. Deere & Co., 478 F. Supp. 411 (C.D. Ill. 1979), vacated on jurisdictional grounds, 623 F.2d 1207 (7th Cir. 1980), the court held that no genuine issue of material fact was created by affidavits contradicting admissions of the patent owner and inventors. In the present case, Auld’s affidavits do not contradict the crucial testimony of the inventor and are thus even less capable of creating a genuine issue of material fact.

...  

In sum, the magistrate did not err in determining: (1) that no genuine material issue of fact was present; (2) that the uncontradicted facts of record establish that the claimed method invention had been commercially exploited more than a year before the crucial date; (3) that no possibility of proving an experimental purpose was present; and (4) that Patent No. 4,100,010 was, therefore, invalid within the intent of 35 U.S.C. § 102(b).

...
The readings in Chapter 1, about the reality of invention that precedes the legal process of patenting, introduced ideas that pertain both to the originality (anti-derivation) requirement of § 102(f) and the “first to invent” priority regime established in § 102(g). This remainder of the cases here take us back into § 102 more thoroughly, to explore the two remaining subsections that one must master in patent law—(e) and (g). And a full understanding of those two parts of § 102 requires that we also consider international frameworks for pursuing patent protection on one invention in multiple foreign states as well as one’s home country.

§ 102(e)


Alexander Milburn Co. v. Davis-Bournonville Co.

270 U.S. 390 (1926)

Holmes, Justice:

This is a suit for the infringement of the plaintiff’s patent for an improvement in welding and cutting apparatus alleged to have been the invention of one Whitford. The suit embraced other matters but this is the only one material here. The defense is that Whitford was not the first inventor of the thing patented, and the answer gives notice that to prove the invalidity of the patent evidence will be offered that one Clifford invented the thing, his patent being referred to and identified. The application for the plaintiff’s patent was filed on March 4, 1911, and the patent was issued June 4, 1912. There was no evidence carrying Whitford’s invention further back. Clifford’s application was filed on January 31, 1911, before Whitford’s, and his patent was issued on February 6, 1912. It is not disputed that this application gave a complete and adequate description of the thing patented to Whitford, but it did not claim it. The District Court gave the plaintiff a decree, holding that, while Clifford might have added this claim to his application, yet as he did not, he was not a prior inventor. The decree was affirmed by the Circuit Court of Appeals. There is a conflict between this decision and those of other Circuit Courts of Appeals … . Therefore a writ of certiorari was granted by this Court.

The patent law authorizes a person who has invented an improvement like the present, ‘not known or used by others in this country, before his invention,’ &c., to obtain a patent for it. Rev. Sts. § 4886, amended, March 3, 1897, c. 391, § 1, 29 Stat. 692. Among the defences to a suit for infringement the fourth specified by the statute is that the patentee ‘was not the original and first inventor or discoverer of any material and substantial part of the thing patented.’ Rev. Sts. § 4920, amended, March 3, 1897, c. 391, § 2, 29 Stat. 692. Taking these words in their natural sense as they would be read by the common man, obviously one is not the first inventor if, as was the case here, somebody else has made a complete and adequate description of the thing claimed before the earliest moment to which the alleged inventor can carry his invention back. But the words cannot be taken quite so simply. In view of the gain to the public that the patent laws mean to secure we assume for purposes of
decision that it would have been no bar to Whitford’s patent if Clifford had written out his prior description and kept it in his portfolio uncommunicated to anyone. More than that ... it is said, at all events for many years, the Patent Office has made no search among abandoned patent applications, and by the words of the statute a previous foreign invention does not invalidate a patent granted here if it has not been patented or described in a printed publication. Rev. Sts. § 4923. These analogies prevailed in the minds of the Courts below.

On the other hand, publication in a periodical is a bar. This as it seems to us is more than an arbitrary enactment, and illustrates, as does the rule concerning previous public use, the principle that, subject to the exceptions mentioned, one really must be the first inventor in order to be entitled to a patent. Coffin v. Ogden, 18 Wall. 120. We understand the Circuit Court of Appeals to admit that if Whitford had not applied for his patent until after the issue to Clifford, the disclosure by the latter would have had the same effect as the publication of the same words in a periodical, although not made the basis of a claim. The invention is made public property as much in the one case as in the other. But if this be true, as we think that it is, it seems to us that a sound distinction cannot be taken between that case and a patent applied for before but not granted until after a second patent is sought. The delays of the patent office ought not to cut down the effect of what has been done. The description shows that Whitford was not the first inventor. Clifford had done all that he could do to make his description public. He had taken steps that would make it public as soon at the Patent Office did its work, although, of course, amendments might be required of him before the end could be reached. We see no reason in the words or policy of the law for allowing Whitford to profit by the delay and make himself out to be the first inventor when he was not so in fact, when Clifford had shown knowledge inconsistent with the allowance of Whitford’s claim and when otherwise the publication of his patent would abandon the thing described to the public unless it already was old. McClain v. Ortmayer, 141 U.S. 419, 424; Underwood v. Gerber, 149 U.S. 224, 230.

The question is not whether Clifford showed himself by the description to be the first inventor. By putting it in that form it is comparatively easy to take the next step and say that he is not an inventor in the sense of the statute unless he makes a claim. The question is whether Clifford’s disclosure made it impossible for Whitford to claim the invention at a later date. The disclosure would have had the same effect as at present if Clifford had added to his description a statement that he did not claim the thing described because he abandoned it or because he believed it to be old. It is not necessary to show who did invent the thing in order to show that Whitford did not.

As to the analogies relied upon below, the disregard of abandoned patent applications, however explained, cannot be taken to establish a principle beyond the rule as actually applied. As an empirical rule it no doubt is convenient if not necessary to the Patent Office, and we are not disposed to disturb it, although we infer that originally the practice of the Office was different. The policy of the statute as to foreign inventions obviously stands on its own footing and cannot be applied to
domestic affairs. The fundamental rule we repeat is that the patentee must be the first inventor. The qualifications in aid of a wish to encourage improvements or to avoid laborious investigations do not prevent the rule from applying here.

Decree reversed.


A person shall be entitled to a patent unless … (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent[.]

Hazeltine Research, Inc. v. Brenner

382 U.S. 252 (1965)

Black, Justice:

The sole question presented here is whether an application for patent pending in the Patent Office at the time a second application is filed constitutes part of the “prior art” as that term is used in 35 U.S.C. § 103 which reads in part:

A patent may not be obtained *** if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art *** .

The question arose in this way. On December 23, 1957, petitioner Robert Regis filed an application for a patent on a new and useful improvement on a microwave switch. On June 24, 1959, the Patent Examiner denied Regis’ application on the ground that the invention was not one which was new or unobvious in light of the prior art and thus did not meet the standards set forth in § 103. The Examiner said that the invention was unpatentable because of the joint effect of the disclosures made by patents previously issued, one to Carlson (No. 2,491,644) and one to Wallace (No. 2,822,526). The Carlson patent had been issued on December 20, 1949, over eight years prior to Regis’ application, and that patent is admittedly a part of the prior art insofar as Regis’ invention is concerned. The Wallace patent, however, was pending in the Patent Office when the Regis application was filed. The Wallace application had been pending since March 24, 1954, nearly three years and nine months before Regis filed his application and the Wallace patent was issued on February 4, 1958, 43 days after Regis filed his application.1

After the Patent Examiner refused to issue the patent, Regis appealed to the Patent Office Board of Appeals on the ground that the Wallace patent could not be properly considered a part of the prior art because it had been a “co-pending patent” and its disclosures were secret and not known to the public. The Board of Appeals rejected this argument and affirmed the decision of the Patent Examiner. Regis and Hazeltine, which had an interest as assignee, then instituted the present action.

1 It is not disputed that Regis’ alleged invention, as well as his application, was made after Wallace’s application was filed. There is, therefore, no question of priority of invention before us.
in the District Court pursuant to 35 U.S.C. § 145 to compel the Commissioner to issue the patent. The District Court agreed with the Patent Office that the co-pending Wallace application was a part of the prior art and directed that the complaint be dismissed. On appeal the Court of Appeals affirmed per curiam. We granted certiorari to decide the question of whether a co-pending application is included in the prior art, as that term is used in 35 U. S. C. § 103.

Petitioners’ primary contention is that the term “prior art,” as used in § 103, really means only art previously publicly known. In support of this position they refer to a statement in the legislative history which indicates that prior art means “what was known before as described in section 102.” They contend that the use of the word “known” indicates that Congress intended prior art to include only inventions or discoveries which were already publicly known at the time an invention was made.

If petitioners are correct in their interpretation of “prior art,” then the Wallace invention, which was not publicly known at the time the Regis application was filed, would not be prior art with regard to Regis’ invention. This is true because at the time Regis filed his application the Wallace invention, although pending in the Patent Office, had never been made public and the Patent Office was forbidden by statute from disclosing to the public, except in special circumstances, anything contained in the application.

The Commissioner, relying chiefly on Alexander Milburn Co. v. Davis-Bournonville Co., 270 U. S. 390, contends that when a patent is issued, the disclosures contained in the patent become a part of the prior art as of the time the application was filed, not, as petitioners contend, at the time the patent is issued. In that case a patent was held invalid because, at the time it was applied for, there was already pending an application which completely and adequately described the invention.

In its revision of the patent laws in 1952, Congress showed its approval of the holding in Milburn by adopting 35 U.S.C. § 102(e). Petitioners suggest, however, that the question in this case is not answered by mere reference to § 102(e), because in Milburn, which gave rise to that section, the co-pending applications described the same identical invention. But here the Regis invention is not precisely the same as that contained in the Wallace patent, but is only made obvious by the Wallace patent in light of the Carlson patent. We agree with the Commissioner that this distinction is without significance here. While we think petitioners’ argument with regard to § 102(e) is interesting, it provides no reason to depart from the plain holding and reasoning in the Milburn case. The basic reasoning upon which the Court decided the Milburn case applies equally well here. When Wallace filed his

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3 35 U.S.C. § 122 states: “Applications for patents shall be kept in confidence by the Patent Office and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances as may be determined by the Commissioner.”
applicatin, he had done what he could to add his disclosures to the prior art. The
rest was up to the Patent Office. Had the Patent Office acted faster, had it issued
Wallace’s patent two months earlier, there would have been no question here. As
Justice Holmes said in Milburn, “[t]he delays of the patent office ought not to cut
down the effect of what has been done.”

To adopt the result contended for by petitioners would create an area where pa-
tents are awarded for unpatentable advances in the art. We see no reason to read
into § 103 a restricted definition of “prior art” which would lower standards of pa-
tentability to such an extent that there might exist two patents where the Congress
has plainly directed that there should be only one.

Affirmed.

Mueller’s Patent Law: 672-675

In re Hilmer

359 F.2d 859 (CCPA 1966)

Rich, Judge:

The sole issue is whether a majority of the Patent Office Board of Appeals erred
in overturning a consistent administrative practice and interpretation of the law of
nearly forty years standing by giving a United States patent effect as prior art as of a
foreign filing date to which the patentee of the reference was entitled under 35

Because [the board] held that a U.S. patent, cited as a prior art reference under
35 U.S.C. § 102(e) and § 103, is effective [as a prior art reference] as of its foreign
“convention” filing date, relying on 35 U.S.C. § 119, the board affirmed the rejec-
tion of claims 10, 16, and 17 of application serial No. 750,887, filed July 25, 1958,
for certain sulfonyl ureas.

This opinion develops the issue, considers the precedents, and explains why, on
the basis of legislative history, we hold that § 119 does not modify the express pro-
vision of § 102(e) that a reference patent is effective as of the date the application
for it was “filed in the United States.”

The two “references” relied on are:

• Habicht 2,962,530 Nov. 29, 1960 (filed in the United States January
  23, 1958, found to be entitled to priority as of the date of filing in Switze-
  rland on January 24, 1957)

• Wagner et al. 2,975,212 March 14, 1961 (filed in the United States May
  1, 1957)

The rejection here is the aftermath of an interference (No. 90,218) between
appellants and Habicht, a priority dispute in which Habicht was the winning party
on a single count. He won because appellants conceded priority of the invention of
the count to him. The earliest date asserted by appellants for their invention is their
German filing date, July 31, 1957, which, we note, is a few months later than
Habicht’s priority date of January 24, 1957.
After termination of the interference and the return of this application to the examiner for further ex parte prosecution, the examiner rejected the appealed claims on Habicht, as a primary reference, in view of Wagner et al., as a secondary reference, holding the claimed compounds to be "unpatentable over the primary reference in view of the secondary reference which renders them obvious to one of ordinary skill in the art."

... The board, one member dissenting with an opinion, affirmed the rejection. ...

... There is in [the board's opinion] an implicit assumption that if the patent is "entitled to the date of a prior foreign application," it is entitled to it, and that is that. But one must examine closely into what is meant by the word "entitled." In essence, that is the problem in this appeal and we wish to point to it at the outset to dispel any mistaken assumptions. A patent may be "entitled" to a foreign filing date for some purposes and not for others, just as a patent may be "used" in two ways. A patent owner uses his patent as a legal right to exclude others, granted to him under 35 U.S.C. § 154. Others, wholly unrelated to the patentee, use a patent, not as a legal right, but simply as evidence of prior invention or prior art, i.e., as a "reference." This is not an exercise of the patent right. This is how the Patent Office is "using" the Habicht patent. These are totally different things, governed by different law, founded on different theories, and developed through different histories.

We have seen that 35 U.S.C. § 119 is involved with respect to the so-called "priority date" of the Habicht reference patent. The other statutory provision involved in this case, applicable to both of the references, is 35 U.S.C. § 102(e). Section 102 has been aptly described as containing "patent defeating provisions." They fall into two classes, events prior to an applicant's date of invention and events prior to filing his U.S. application, related respectively to the requirement of novelty and to provisions for loss of right through delay in filing after certain events have made the invention public. Subsection (e) is one of the novelty provisions, one of the "conditions for patentability," and if the facts of an applicant's case bring him within it, his right to a patent is defeated. ...

Thus, though both references here were patents copending with appellants’ application, issuing after it was filed, 102(e) makes them available as of their U.S. filing dates which are earlier than appellants' U.S. filing date. However, since 102(e) refers to the applicant's date of invention, not to his filing date, he is entitled to an opportunity to establish his date of invention to show that his invention possessed statutory novelty when he made it. In this case appellants did this by showing that they filed a German application earlier than the U.S. filing dates of the references, specified in 102(e), and that they were entitled to its date for "priority" under section 119. This right is not in question. The board ruled:

Appellants have overcome the U.S. filing date of Habicht by claiming the benefit under 35 USC 119 of an application filed in Germany on July 31, 1957. The specification of this German application has been examined and is found to contain a full disclosure of the subject matter of the claims, and the U.S. filing date of Habicht is considered overcome.
We can now summarize the issue and simultaneously state the board’s decision. Continuing the above quotation, the board said:

The Examiner insists, however, that the effective date of the Habicht patent is January 24, 1957, the date of an application filed in Switzerland which is claimed by Habicht under 35 USC 119. Appellants have not overcome this earlier date of Habicht. The issue is hence presented of whether the foreign priority date of a United States patent can be used as the effective filing date of the patent when it is used as a reference.

***

Our conclusion is that the priority date governs ***.

This is the decision alleged to be in error. We think it was error.

Background of the Issue as to the Availability of Habicht as a Reference

The issue in this case involves a question of statutory interpretation basic to the operation of the patent system. This issue has arisen because after decades of a uniform practice, and interpretation of law which has existed in part since 1903 and in whole since 1926, the Patent Office has made an abrupt about-face; having refused for at least 30 years, after expressly ruling on the question, to apply U.S. patents as references as of foreign “priority” dates, it has changed its practice as made manifest in an unknown number of board decisions. One of them is here on appeal. …

There has been a spate of writing on the question of law here involved, all of which we have read. The same ground has been plowed and replowed by authors as well as different panels of the Patent Office Board of Appeals. …

…

We find it indeed strange that it has suddenly become imperative to reinterpret a statute which was enacted in 1903, later construed in the light of a Supreme Court decision of 1926, and to invert a practice under which a generation of lawyers since the latter date has obtained for clients close to two million United States patents, counting for their validity on a construction of the statutory law not only followed but promulgated by the Patent Office. Furthermore, in 1952 this law, already a quarter of a century old in toto, was carried forward by Congressional action without change, insofar as it was already statutory, and insofar as it was case law it was codified without change, the particulars of which will be dealt with later. This change in long and continuous administrative practice has also been made without any advance notice, hearing, or stated basis in policy, economics, or international relations. While it may be that the world is shrinking and the very concept of “foreign” should be abolished for the good of mankind, this is not a constitution we are expounding but specific statutes enacted to accomplish specific purposes, the meaning of which should stay put, absent intervening Congressional modifications, for well-understood reasons.

Turning from the general to the specific, we will now consider our specific reasons for construing the applicable statutes as they have for so long been construed, contrary to the recent innovation of the Patent Office.

…
The board’s construction is based on the idea that the language of the statute is plain, that it means what it says, and that what it says [in § 119] is that the application filed abroad is to have the same effect as though it were filed here—for all purposes. We can reverse the statement to say that the actual U.S. application is to have the same effect as though it were filed in the U.S. on the day when the foreign application was filed, the whole thing being a question of effective date. We take it either way because it makes no difference here.

Before getting into history, we note first that there is in the very words of the statute a refutation of this literalism. It says “shall have the same effect” and it then says “but” for several situations it shall not have the same effect, namely, it does not enjoy the foreign date with respect to any of the patent-defeating provisions based on publication or patenting anywhere in the world or public use or being on sale in this country more than one year before the date of actual filing in this country.\footnote{These patent-defeating … time-bars are also contained in 35 U.S.C. § 102(b) and have always been included in § 119 to assure that it would not have the “same effect” if giving effect to a priority date would avoid these time-bars.}

As to the other statute involved, we point out that the words of § 102(e), which the board “simply” reads together with § 119, also seem plain. Perhaps they mean precisely what they say in specifying, as an express patent-defeating provision, an application by another describing the invention but only as of the date it is “filed in the United States.”

The great logical flaw we see in the board’s reasoning is in its premise (or is it an a priori conclusion?) that “these two provisions must be read together.” Doing so, it says § 119 in effect destroys the plain meaning of § 102(e) but the board will not indulge the reverse construction in which the plain words of § 102(e) limit the apparent meaning of § 119. We see no reason for reading these two provisions together and the board has stated none. We believe, with the dissenting board member, that § 119 and § 102(e) deal with unrelated concepts and further that the historical origins of the two sections show neither was intended to affect the other, wherefore they should not be read together in violation of the most basic rule of statutory construction, the “master rule,” of carrying out the legislative intent. Additionally, we have a long and consistent administrative practice in applying an interpretation contrary to the new view of the board, confirmed by legislation ratification in 1952. We will consider these matters separately.

Section 119

We shall now take up the history and purpose of § 119. The board opinion devotes the equivalent of four pages in the printed record to a scholarly and detailed review of the history of § 119 with all of which we agree, except for the interwoven conclusions as to its meaning as it bears on the effective date of a U.S. patent used as a reference.

The board shows that the predecessor statute (R.S. 4887), containing the words “shall have the same force and effect,” was enacted March 3, 1903 (32 Stat. 1225). Theodore Roosevelt signed it into law. The bill was drafted and proposed by a Commission created by Act of Congress in 1898 (30 Stat. 431) to study the effect
of the Convention of Paris for the Protection of Industrial Property of 20th March 1883, which was under revision at Brussels even as the Commission deliberated, the revision being adopted at Brussels on 14th December 1900. (It was last revised at Lisbon on 31st October 1958.) The Commission made a report November 27, 1900, printed in 1902, entitled Report of the Commissioners Appointed to Revise the Laws Relating to Patents, Trademarks, and Trade Names, with Reference to Existing Conventions and Treaties, which is fairly descriptive of its purpose. …

Under the heading “Priority Under the Convention,” it says (p. 12):

The second provision of the Convention to be noticed, and one which may be of very great advantage to those of our citizens who desire to secure patents in foreign countries for their inventions, is that contained in article 4, and relates to the so called “delay of priority,” or “period of priority.”

It then explained that in most countries no valid patent can be obtained if before the application is filed, the invention has been described in a printed publication, either in the country of application or even, as in the case of France and six other countries, in any country; that the same was true as to public use of the invention; and that the convention gives applicants in member countries a period (then 7 months, soon extended to 12) in which they can file applications in other countries after the filing in their own country and obtain valid patents notwithstanding publication or use in the interval and before the filing of the foreign application. This, it explained, is the “delay of priority.” In plain English, it was the right of an applicant to have the foreign application treated at law as prior to the intervening publication or public use, though in fact it was not, by giving a right to that applicant to delay filing in the foreign country, instead of filing simultaneously with the home application, yet have it treated as though filed on the date of the home application. This is what today we call simply “Convention priority,” or just “priority.” The foreign filing date is the “convention date” or the “priority date.”

This priority right was a protection to one who was trying to obtain patents in foreign countries, the protection being against patent-defeating provisions of national laws based on events intervening between the time of filing at home and filing abroad. Under the heading “Recapitulation of Advantages Secured by the Convention,” the Commission said, so far as relevant here (pp. 14-15):

The advantages to our citizens in the matter of patents directly afforded by the convention may be thus recapitulated.

First. The enjoyment in foreign countries of equal rights with subjects or citizens of those countries.

Second. The “delay of priority” of seven months within which to file applications abroad after filing in this country.

Third. The privilege of introducing articles embodying the invention manufactured in this country into foreign countries to a certain extent without thereby causing the forfeiture of the patents taken out there.

Note the emphasis repeatedly placed in the Commission Report on advantages to United States citizens. It was felt we should do what was necessary to comply with
the reciprocity provisions to enjoy the benefits of the convention for our own citizens. ...

Specific to the question here, the Commission Report says (p. 24):

We are, therefore, of the opinion that an amendment to the law should be made, providing that the foreign application shall have, in case an application is filed in this country by the applicant abroad within the specified period, the same effect as if filed here on the day it was filed abroad.

...

For the foregoing reasons, we are clearly of the opinion that § 119 is not to be read as anything more than it was originally intended to be by its drafters, the Commission appointed under the 1898 Act of Congress, namely, a revision of our statutes to provide for a right of priority in conformity with the International Convention, for the benefit of United States citizens, by creating the necessary reciprocity with foreign members of the then Paris Union.

...

Section 102(e)

We have ... pointed out that [this section] is a patent-defeating section, by contrast with § 119 which gives affirmative “priority” rights to applicants notwithstanding it is drafted in terms of “An application.” The priority right is to save the applicant (or his application if one prefers to say it that way) from patent-defeating provisions such as § 102(e); and of course it has the same effect in guarding the validity of the patent when issued.

Section 102(e), on the other hand, is one of the provisions which defeats applicants and invalidates patents and is closely related in fact and in history to the requirement of § 102(a) ...

In fact, § 102(e) springs straight from § 102(a)’s predecessor, R.S. 4886, by decision of the United States Supreme Court in 1926. It was pure case law until 1952 when, having become firmly established, that law was codified by incorporating it in the statute.

...

We need not go into the reasoning of the Milburn case, which has its weaknesses, because all that matters is the rule of law it established: That a complete description of an invention in a U.S. patent application, filed before the date of invention of another, if it matures into a patent, may be used to show that that other was not the first inventor. This was a patent-defeating, judge-made rule and now is § 102(e). The rule has been expanded somewhat subsequent to 1926 so that the reference patent may be used as of its U.S. filing date as a general prior art reference, as shown by ... the December 8, 1965 Supreme Court decision in Hazeltine Research, Inc. v. Brenner, 382 U.S. 252.

What has always been pointed out in attacks on the Milburn rule, or in attempts to limit it, is that it uses, as prior knowledge, information which was secret at the time as of which it is used—the contents of U.S. patent applications which are preserved in secrecy, generally speaking, 35 U.S.C. § 122. This is true, and we think
there is some validity to the argument that that which is secret should be in a different category from knowledge which is public. Nevertheless we have the rule. However, we are not disposed to extend that rule, which applies to the date of filing applications in the United States, the actual filing date when the disclosure is on deposit in the U.S. Patent Office and on its way, in due course, to publication in an issued patent.

The board’s new view, as expressed in this case and in the *Zemla* and *Rapala* decisions ..., has the practical potential effect of pushing back the date of the unpublished, secret disclosures, which ultimately have effect as prior art references in the form of U.S. patents, by the full one-year priority period of § 119. We think the *Milburn* rule, as codified in § 102(e), goes far enough in that direction. We see no valid reason to go further, certainly no compelling reason.

We have seen that § 119 originated in 1903 and that its purpose was to grant protective priority rights so that the United States might be a participating member in the International Convention by giving reciprocal priority rights to foreign applicants with respect to the obtaining of patents. We have also seen that § 102(e) was the codification of a court-developed patent-defeating rule based on a statutory requirement that an applicant’s invention must not have been previously known by others in this country. We see no such relation between these two rules of law as requires them to be read together and it is our view that § 119 should not be so read with § 102(e) as to modify the express limitation of the latter to applications “filed in the United States.”

... *In re Giacomini*

612 F.3d 1380 (Fed. Cir. 2010)

*Rader, Chief Judge:*

Peter Joseph Giacomini, Walter Michael Pitio, Hector Francisco Rodriguez, and Donald David Shugard (collectively, “Giacomini”) appeal from a decision of the Board of Patent Appeals and Interferences rejecting certain claims of U.S. Patent Application No. 09/725,737 as anticipated under 35 U.S.C. § 102. Giacomini argues that the anticipatory reference—U.S. Patent No. 7,039,683, the Tran patent—does not qualify as prior art because Giacomini’s filing date antedates the Tran patent’s filing date. Because the Tran patent has a patent-defeating effect as of the filing date of the provisional application to which it claims priority and which was filed before Giacomini’s application, this court affirms.

I.

Giacomini’s application—“Method and Apparatus for Economical Cache Population”—was filed on November 29, 2000. The application claims a technique for selectively storing electronic data in a readily accessible memory called a “cache.” When a system retrieves requested data from a source, it stores the data in its cache so that it can retrieve the data more quickly next time. Because the cache has a limited space, the system must selectively store data. Giacomini’s technique populates the cache with data only when the system receives a certain number of requests for that data. Claim 1 is representative:
A method comprising:

populating a cache with a resource only when at least \( i \) requests for said resource have been received;

wherein \( i \) is an integer and is at least occasionally greater than one.

This cache does not normally include infrequently requested data because it “at least occasionally” stores data for which multiple requests have been made. Claims 1, 2, 8, 11, 12, 15, 22-24, 27, 28, 31, and 32 of Giacomini’s application are at issue on appeal.

II.

The Board rejected certain claims of Giacomini’s application as anticipated under 35 U.S.C. § 102 by the Tran patent, and, in the alternative, by U.S. Patent No. 6,463,509 (“the Teoman patent”).

The Tran patent—“Electronic Information Caching”—describes a caching technique based on an anticipated demand for data. Its “anticipating module” considers “past requests for access to the same or related electronic information by access requesters.” Tran patent, col. 1, ll. 49-52. Such “past requests for information may be measured by the frequency or volume of access requests.” Id. col. 3, ll. 25-28. The Board found, and Giacomini does not dispute, that the Tran patent teaches all of the claimed features in Giacomini’s application.

The central issue at the Board was the eligibility of the Tran patent to serve as prior art under 35 U.S.C. § 102(e). The Tran patent’s filing date is December 29, 2000, exactly a month after Giacomini filed his application. However, the Tran patent claims priority to a provisional application (“the Tran provisional”) filed on September 25, 2000, which antedates Giacomini’s filing date. Therefore, the Board held that the Tran patent has a patent-defeating effect as of the filing date of the Tran provisional.

Giacomini appeals the Board’s decision that the Tran patent and the Teoman patent each anticipates his application. …

III.

This court reviews the Board’s legal conclusions, including statutory interpretation, without deference. In re Swanson, 540 F.3d 1368, 1374-75 (Fed. Cir. 2008). Anticipation is a question of fact. In re Gleave, 560 F.3d 1331, 1334-35 (Fed. Cir. 2009). This court reviews the Board’s factual determinations for substantial evidence. Id.

IV.

Section 102 governs the conditions of patentability. The statute, in pertinent part, states:

[A] person shall be entitled to a patent unless *** the invention was described in *** (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent[.]

35 U.S.C. § 102(e)(2) (emphasis added). An application that a patent was “granted on” is the first U.S. application to disclose the invention claimed in the patent. In re
Klesper, 397 F.2d 882, 885-86 (CCPA 1968). Title 35 further clarifies that “[t]he provisions of this title relating to applications for patent shall apply to provisional applications for patent, except as otherwise provided, and except *** [in] sections 115, 131, 135, and 157 of this title.” 35 U.S.C. § 111(b)(8). Under this encompassing rule, “applications for patent” under § 102 includes both provisional and non-provisional patent applications. Therefore, an applicant is not entitled to a patent if another’s patent discloses the same invention, which was carried forward from an earlier U.S. provisional application or U.S. non-provisional application.

As noted, Giacomini does not dispute that the Tran patent describes the invention claimed in Giacomini’s application. Also, the Tran provisional, which antedates Giacomini’s filing date, was the first U.S. application to describe the invention. The Board found that “[t]he Provisional Application No. 60/234,996, from which Tran claims priority under 35 U.S.C. § 119(e), discloses that ‘[a]nticipating requests for electronic information *** is generally performed based on one or more criteria, e.g., past requests for information.’” Section 119(e) treats a nonprovisional application as though filed on the date of its corresponding provisional application. Section 119 recites:

(c)(1) An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. ***


An important limitation is that the provisional application must provide written description support for the claimed invention. Because Giacomini never argued before the Board that the Tran provisional failed to provide written description support for the claimed subject matter in accordance with § 119(e), Giacomini waived the argument by failing to raise it below. See In re Watts, 354 F.3d 1362, 1368 (Fed. Cir. 2004) (declining to consider arguments that the applicant failed to contest before the Board); In re Berger, 279 F.3d 975, 984 (Fed. Cir. 2002) (same). Therefore, the Tran patent “shall have the same effect,” including a patent-defeating effect, as to the claimed invention as though it was filed on the date of the Tran provisional. Accordingly, Giacomini, who filed his application after Tran filed his provisional application, cannot receive a patent covering the same subject matter under 35 U.S.C. § 102(e).

This conclusion is consistent with “[t]he fundamental rule *** that the patentee must be the first inventor.” Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 402 (1926). In Milburn, the Supreme Court held that a patent applied for before but not granted until after a second patent is sought bars the issuance of the second patent. Id. at 400-01. The rule stems from the principle that,
subject to certain exceptions, “one really must be the first inventor in order to be entitled to a patent.” *Id.* at 400. Although *Milburn* concerned a nonprovisional application, a provisional application similarly shows that someone else was the first to invent. See id. at 400 (“[O]bviously one is not the first inventor if *** somebody else has made a complete and adequate description of the thing claimed before the earliest moment to which the alleged inventor can carry his invention back.”). The Tran provisional evinces that Tran, and not Giacomini, was the first to invent the claimed subject matter. Allowing Giacomini’s application would create an anomalous result where someone who was not the first to invent in the United States receives a patent.

Giacomini argues that 35 U.S.C. § 119(e) shifts a patent’s priority date but not its effective reference date to the filing date of an earlier provisional application. In other words, Giacomini contends that although the Tran patent claims the benefit of priority to the Tran provisional, the Tran patent does not have a patent-defeating effect as of the Tran provisional’s filing date.

Giacomini’s distinction between priority date and effective reference date largely stems from *In re Hilmer*, 359 F.2d 859 (1966). The issue in *Hilmer* was whether a U.S. patent, cited as a § 102(e) prior art reference, was effective as of its foreign filing date under § 119. *Id.* at 862. This court’s predecessor rejected the Board’s conclusion that “the foreign priority date of a U.S. patent is its effective date as a reference.” *Id.* at 870. The court instead held that “§ 119 only deals with ‘right of priority.’ The section does not provide for the use of a U.S. patent as an anticipatory reference as of its foreign filing date.” *Id.* at 862. Thus, *Hilmer* distinguished a patent’s priority date under § 119 and effective reference date under § 102(e) in cases involving an earlier foreign application. Giacomini equates a U.S. provisional application to a foreign patent application to argue that the Tran provisional’s filing date is not the Tran patent’s effective date as a prior art reference.

But at the time this court’s predecessor decided *Hilmer*, § 119 only governed the benefit of claiming priority to an earlier filing date in foreign countries. *Id.* at 862. Congress added § 119(e) along with the enactment of provisional applications in 1994. See Uruguay Round Agreements Act, Pub. L. 103-465, 108 Stat. 4809 (1994). Therefore, broad language in *Hilmer* concerning § 119 is not applicable to provisional applications. Also, Giacomini misses an important distinction between *Hilmer* and the present case. *Hilmer* involved an earlier foreign application while the present case deals with an earlier U.S. provisional application. See *Klesper*, 397 F.2d at 885 (*Hilmer* clarified that “domestic and foreign filing dates stand on entirely different footings.”).

Section 102(e) codified the “history of treating the disclosure of a U.S. patent as prior art as of the filing date of the earliest U.S. application to which the patent is entitled, provided the disclosure was contained in substance in the said earliest application.” *Id.* (emphasis added). According to *Hilmer*, an earlier foreign application does not shift a corresponding patent’s effective reference date because § 102(e) explicitly requires the earlier application to be “filed in the United States.” *Hilmer*, 359 F.2d at 862 (quoting 35 U.S.C. § 102(e)). This court’s predecessor warned that § 119 cannot be read with § 102(e) to modify the express domestic limitation.
In contrast, an earlier provisional application is an application “filed in the United States.” 35 U.S.C. § 102(e). Treating a provisional application’s filing date as both the patent’s priority date and its effective reference date does not raise the alleged tension between §§ 102(e) and 119. Given the “clear distinction between acts abroad and acts here,” Hilmer, 359 F.2d at 879, Giacomini’s reliance on Hilmer is misplaced. Id.

Accordingly, the Tran patent has a patent-defeating effect as of the filing date of the Tran provisional, or September 25, 2000. Giacomini did not file his application until months after Tran filed his provisional application. Giacomini is not the first to invent in the United States and thus is not entitled to a patent. Because this court affirms the Board’s finding of anticipation based on the Tran patent, this court will not review the Board’s finding with respect to the Teoman patent.

§ 102(g)

Litchfield v. Eigen
535 F.2d 72 (CCPA 1976)

Rich, Judge:

This appeal is from the decision of the Patent and Trademark Office Board of Patent Interferences awarding priority to the senior party-patentee Eigen1 against the junior party-applicants Litchfield and Vely2 as to both counts in interference on the ground that Litchfield and Vely, although having been first to conceive, failed to show reasonable diligence from just prior to Eigen’s conception to their reduction to practice. We affirm.

The Contested Subject Matter

The invention in interference is an oral composition, useful for the prevention of dental caries and calculus. The counts are:

1. An oral composition comprising an effective amount up to 6.25% of a nontoxic, non-volatile material selected from the group consisting of the aliphatic aldehyde glutaraldehyde and the aliphatic aldehyde oxyderivative glyoxylic acid and a dental vehicle.

2. An oral composition in accordance with count 1, wherein the aldehyde ingredient constitutes .05–6.25% by weight of the composition.

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1 Eigen is a party on the basis of his U. S. Patent No. 3,497,590, entitled “Oral Compositions Containing Non-Toxic, Non-Volatile Aliphatic Aldehyde,” the application for which was filed August 24, 1967. The patent is assigned to Colgate-Palmolive Company.

Both parties claim to have made the invention in the course of research of somewhat broader scope. Their invention histories, as set out in the board’s findings of fact, are helpful to an understanding of the issues.

A. Litchfield and Vely

Litchfield and Vely were employees of the Battelle Memorial Institute at Columbus, Ohio. In February 1962, the L. A. Dreyfus Co., a wholly-owned subsidiary of their assignee Wrigley, engaged the services of Battelle to search for anticaries agents that were nontoxic, “non-pharmaceutical” (non-prescription?) and suitable for incorporation into chewing gum. Litchfield, Vely and Arthur C. Peters comprised the Battelle research team for the project. They selected candidate anticaries agents and tested them in vitro by microbiological assay. If a candidate anti-carries agent showed a significant level of activity in vitro, it was considered for further testing in vivo. During 1962 and 1963, the research team determined that various water-soluble aldehydes should be investigated. On April 3, 1964, Vely and his assistant, Powell, tested a solution of glutaraldehyde in vitro in concentrations of 0.1%, 0.05%, and 0.025% against Streptococcus faecalis strain FA-1. No later than April 14, 1964, Vely and Powell further tested glutaraldehyde in vitro against Lactobacillus casei ATCC 4646. As a result of these tests, Litchfield and Vely concluded that glutaraldehyde showed significant activity. There was no further activity with respect to glutaraldehyde until the period September 8, 1965, through December 8, 1965, when, under Peters’ supervision, a 1% solution of glutaraldehyde was tested in vivo in rats. On April 13, 1966, a report, signed by Litchfield, was issued by Battelle to Wrigley classifying glutaraldehyde in the “1-plus” category, which Peters explained meant that the test results showed about a 25% reduction in caries incidence in vivo.

B. Eigen

Eigen was section head of biochemistry at Colgate-Palmolive Company. Beginning about May 1964, Don N. Harris, a biochemist at Colgate, came under Eigen’s supervision and was assigned a project of determining whether aldehydes were effective in inhibiting dental calculus. Eigen claims to have suggested using glutaraldehyde as an anti-calculus agent to Harris early in 1964; Harris, however, was unable to recall when testifying many years later, who specifically suggested the testing of glutaraldehyde. In any event, Harris entered aldehydes as possible anti-calculus agents in his notebook on April 23, 1964. On May 22, 1964, using an in vitro procedure, he tested glutaraldehyde in concentrations of 1.25%, 2.5%, and 6.25%. Based on these tests, Harris concluded that glutaraldehyde appeared to be a potential anticalculus agent. Harris discussed his conclusions from the in vitro tests with Eigen, and it was decided that glutaraldehyde should be tested in vivo. On June 25, 1964, Harris completed an in vivo test of glutaraldehyde in rats. Based on this test, Harris concluded that a 2.5% solution of glutaraldehyde produced a statistically significant reduction of calculus.

The Board’s Opinion

The board noted that at final hearing Eigen admitted that Litchfield and Vely had established conception in April 1964; the board stated that the specific date was April 3, 1964, when Vely and Powell tested glutaraldehyde solutions in vitro against Streptococcus faecalis strain FA-1. As to an actual reduction to practice by Litchfield
and Vely, the board found that a glutaraldehyde composition falling within the scope of the counts was composed on behalf of Litchfield and Vely during the period September-December 1965 for the purpose of testing glutaraldehyde in vivo as an anticasies agent and that the utility of the composition was demonstrated when it was determined that the composition had an anti-caries activity in the “1-plus” category, i.e., when it was demonstrated that the composition decreased caries by about 25% as compared with control animals. Even though the in vivo test was completed in December 1965, the board did not accord Litchfield and Vely that date for a reduction to practice; rather, it accorded them the date of the April 13, 1966, report by Battelle to Wrigley, wherein “the first contemporaneous recognition of a 1-plus activity for glutaraldehyde by Litchfield appears ***.”

As to Eigen, the board stated that it believed “on the basis of the record before us, that Eigen conceived of the use of glutaraldehyde as an anti-calculus agent and that Harris tested glutaraldehyde in vitro on behalf of Eigen.” The board accorded Eigen a conception date no earlier than May 22, 1964, since “the first corroborated documentary evidence relating to Eigen’s conception appears in Harris’ notebook dated May 22, 1964 ***.” That entry sets out Harris’ in vitro test of glutaraldehyde. The board found an actual reduction to practice by Eigen on June 25, 1964, when “Harris—on behalf of Eigen—completed an in vivo test using a 2.5% solution of glutaraldehyde in rats and concluded from the test that glutaraldehyde produced a significant reduction of calculus,” since the solution fell within the counts and a practical utility was demonstrated therefor.

Despite the earlier April 3, 1964, conception date accorded Litchfield and Vely, the board awarded priority to Eigen because Litchfield and Vely had not met their “affirmative burden of showing reasonable diligence” in that they had “not shown any affirmative action toward an actual reduction to practice *** from May 21, 1964 [the day prior to Eigen’s conception] *** to September 8, 1965 *** when in vivo tests were begun,” nor had they shown an acceptable excuse or reason for their failure to take affirmative action during that period. The board was not persuaded by the assertion of Litchfield and Vely that the record excused their failure to take affirmative action during the critical period because it established that they were testing many other compounds according to “the regular procedure for testing compounds in order, within budgetary limits as animals became available ***.” The board stated that Litchfield and Vely had not offered “a detailed explanation pointing out when compounds were selected and tested.”

Appellants’ Arguments

Litchfield and Vely argue that Eigen did not establish conception and reduction to practice by corroborated evidence because neither Harris’ oral testimony nor the documentary evidence presented establish conception by Eigen. Specifically, they state that Harris’ testimony did not corroborate conception by Eigen because Harris was unable to recall who suggested that he test glutaraldehyde. Litchfield and Vely also state that there is no indication in any document of record that Eigen was responsible for the selection of glutaraldehyde for testing. They point to Harris’ laboratory notebook and state that Eigen’s name appears only as that of a witness to the in vitro test of glutaraldehyde.
Although Litchfield and Vely state that the above argument, if accepted, would moot the issue of diligence, they also argue that they have shown diligence or an excuse for the lack thereof, stating that the board erroneously ignored their exhibits 9-12 and 18 and Peters’ testimony, which they maintain show continuous activity during the critical period. The exhibits are semiannual reports from Battelle to Wrigley summarizing the in vivo work completed during the period January 1, 1964 – February 28, 1967. Litchfield and Vely admit that glutaraldehyde was not tested in vivo between the date established for the last in vitro test, April 14, 1964, and the beginning of the in vivo test on September 8, 1965. They maintain, however, that the summary reports, corroborated by Peters’ testimony, demonstrate their continuous activity “directed to the project,” meaning the research project as a whole, which involved many compounds in addition to glutaraldehyde. Litchfield and Vely explain their delay in testing glutaraldehyde in vivo as being due to “budgetary limitations” and the “availability of animals” for in vivo testing which resulted in a “backlog of compounds successfully tested in vitro which were awaiting available animals for in vivo testing.”

Opinion

The board did not err in according Eigen a conception date of May 22, 1964. To argue that Eigen has not established conception because Harris could not recall who placed glutaraldehyde on the list of aldehydes which he tested in vitro is to ignore the other facts of record which do establish his conception. Those facts appear in documents of record, contrary to the contention of Litchfield and Vely. Paramount among these is the documentary evidence of the in vitro test of glutaraldehyde by Harris. Litchfield and Vely do not contest that this test was conducted as described in Harris’ notebook, nor do they contest the results of that test as set out therein. The notebook shows that glutaraldehyde was among several aldehydes tested in vitro by Harris, and Harris corroborated Eigen in testifying that Eigen assigned him the project of testing aldehydes for their effect on dental calculus. Eigen testified that he originated the concept of using aldehydes as anti-calculus agents; Harris’ notebook corroborates Eigen’s testimony. In Harris’ notebook the following entry appears for April 23, 1964:

“In vitro” Calculus Prevention

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Discussion—Aldehydes have long been known to react with amino groups *** and has [sic] been used in the tanning industry for the tanning of collagen leathers. The ground substance of most mineralization sites has been shown to be collagen (bone, enamel etc.). Other workers have shown that if the amino groups are blocked, then calcification is prevented. We hoped that such a mechanism would apply in the search for a potential anticalculus agent.

Since it is clear that Eigen assigned the testing of aldehydes to Harris, it is reasonable to infer that the rationale set out in the notebook is the one Eigen gave Harris when he made the assignment. Thus, the notebook entry corroborates Eigen’s testimony that his conception of aldehydes as anti-calculus agents was based on earlier work showing that removal of amino groups from an organic matrix with

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nitrous acid resulted in a matrix that did not calcify. The foregoing shows that, at least by April 23, 1964, Eigen had conceived the idea that at least some aldehydes might be useful in the prevention of dental calculus because of their ability to block amino groups. It remained only to “test this theory out,” as Eigen put it, by testing various aldehydes; this seems to be the only reason for testing any of the aldehydes which were tested, including glutaraldehyde. The record shows that Harris tested glutaraldehyde along with several other aldehydes; his notebook entry of May 22, 1964, discussing the results of those tests, states: “From these results, it appears as if aldehydes are combining with amino groups in the ground substance and preventing calcification.” Thus, not only did Harris’ tests show glutaraldehyde to prevent calcification, they showed that the mechanism by which it did so was precisely that postulated by Eigen, for whom the tests were conducted. We conclude that these tests, conducted to test Eigen’s theory, redounded to the benefit of Eigen when they confirmed it, and thus, when Harris obtained the test results confirming Eigen’s theory as to glutaraldehyde on May 22, 1964, it was the same as if Eigen had personally made the tests. As of that date, then, we hold that Eigen had a conception of the potential of glutaraldehyde as an anti-calculus agent.

We find no error in the board’s conclusion that Litchfield and Vely failed to exercise reasonable diligence in reducing their invention to practice. They admit that from their own conception in April 1964 to September 8, 1965, they did not test glutaraldehyde in vivo; in other words, during that period, none of their activity was directed to reducing their invention to practice. It is of no avail to them that their activities were continuously “directed to the project” of testing numerous compounds for anti-caries activity, for this is no explanation at all of why the in vivo testing of glutaraldehyde was delayed. Indeed, the fact that their summary reports for this period show continuous in vivo testing of other compounds indicates that throughout the period in question they possessed the capability of conducting such a test. To state that the delay was due to “budgetary limits established by the sponsor and the availability of animals” for in vivo testing is not enough. Litchfield and Vely have an affirmative duty to show what “budgetary limits” they were operating under and what the “availability of animals” was in order for any tribunal to have the opportunity to determine whether the delay was reasonable in light of these factors. The reasonableness of the delay in light of the facts adduced is essential to excusing non-diligence. Litchfield and Vely have pointed to nothing in the record which shows what budgetary limitations they were working under, nor have they demonstrated how these limitations resulted in the delay in testing glutaraldehyde in vivo. The only evidence pointed to with respect to the availability of animals relates to the time (“several months”) it took from February 1962 to grow the rats necessary for the in vivo testing then being considered. This delay, coming long before the in vitro test of glutaraldehyde by them, is obviously irrelevant. The only backlog pointed to in the record relates to “a backlog of in vivo tests they were going to reach in hamsters.” There is nothing in this testimony as to what this backlog was due to, nor could the witness testify as to whether glutaraldehyde was in that backlog. Litchfield and Vely have not shown what caused the delay in testing glutaraldehyde in vivo, much less that such delay was reasonable. Given the fact, in addition, that Eigen was able to conduct an in vivo test within days of his in vitro test,
the delay of Litchfield and Vely must be viewed as an extraordinary delay, and the lack of explanation thereof is fatal to their assertion of diligence.

\[\text{…}\]

**Peeler v. Miller**

535 F.2d 647 (CCPA 1976)

*Rich, Judge:*

The senior party, Peeler, Godfrey, and Furby (Peeler),\(^1\) appeals from the decision of the Patent and Trademark Office (PTO) Board of Patent Interferences (board), one member dissenting, awarding priority of invention in five counts to the junior party, Miller.\(^2\) We reverse.

**The Subject Matter**

Counts 6 and 8 adequately describe the subject matter:

6. A power transmission fluid consisting essentially of a major portion of a phosphate ester having a tendency to cause cavitation erosion damage, and as an additive effective in reducing such damage, from 0.01 to 10% by weight of a halocarbon containing only halogen atoms and at least one carbon atom having a boiling point below 75°C, wherein the halogen substituents on said halocarbon are chlorine, bromine or fluorine or combinations thereof.

8. A method of inhibiting cavitation damage to a hydraulic system utilizing a hydraulic fluid consisting essentially of a major portion of a phosphate ester, which method comprises maintaining in said hydraulic fluid by addition 0.01 to 10% by weight of a halocarbon containing only halogen atoms and at least one carbon atom having a boiling point below 75°C, wherein the halogen substituents on said halocarbon are chlorine, bromine or fluorine or combinations thereof.

**The Evidence**

Peeler took no testimony and relied on his filing date. Miller submitted testimony in the form of affidavits (by stipulation) from himself, various Monsanto colleagues, and William Black, the Monsanto patent attorney who prepared and filed Miller’s application. Miller’s efforts, culminating in this invention, began in the fall of 1964 when he became aware of serious hydraulic valve leakage in British “Trident” aircraft using Monsanto’s SKYDROL 500A brand hydraulic fluid. He

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\(^2\) Involved on application serial No. 32,344, filed April 27, 1970, entitled “Functional Fluid Compositions Containing Fluro Alkanes,” which is assigned to Monsanto Company.
concluded that cavitation\(^3\) was responsible for the problem and began the search for a fluid additive to overcome the problem.

In 1965, in ultrasonic vibrating probe tests, in which a soft metal tip is vibrated at high frequency in a beaker containing SKYDROL 500A and the additive under test and the loss of metal from the tip measured, it was found that water as an additive would reduce cavitation damage substantially. This laboratory finding was confirmed in use in the Trident aircraft. In March 1966 Miller thought of using Freon 11 \((\text{the DuPont trademark for trichloromonomfluoromethane})\) as the additive and also other halocarbons, which are fire-resistant and, like water, have high volatility in relation to the base fluid, as anti-cavitation additives. On March 8 Miller instructed a colleague (Stainbrook) to conduct ultrasonic vibrating probe tests using Freon 11 as the additive. Stainbrook performed one control run and one run with Freon 11 as the additive on that day. Stainbrook’s affidavit and Miller’s March 14 notebook page indicate that Freon 11 significantly reduced erosion of the probe tip in the experiment. In his notebook entry Miller indicated, “To better assess such additives, we are setting up hermetically sealed sample containers.” The record does not show that hermetically sealed containers were subsequently used by Miller.

On April 5, 1966, Miller submitted a “preliminary disclosure of invention,” which his superiors in the Research Department of Monsanto’s Organic Chemicals Division rated “A (Ready [to file])” on April 18, 1966. Presumably, this disclosure was forwarded to Monsanto’s patent department for action soon thereafter, but the record does not show when this occurred.

From the time when Miller’s invention disclosure was rated “A (Ready)” more than four years elapsed until Miller’s filing date. Miller continued working on cavitation inhibitors of undisclosed nature during this time, and in September 1966 he gave presentations at several U.S. aviation industry meetings on Monsanto’s solution of the Trident valve damage problem. Stainbrook stated that he ran vibrating probe tests in October 1967 using Freon 112(a) \((\text{apparently tetrachlorodifluoroethane})\) as the additive and that he informed Miller of his results. What Miller did with this information is not indicated in the record. Meanwhile, there is no evidence of action in Monsanto’s patent department until the arrival of Mr. Black in October 1968, some two and a half years after Miller’s alleged actual reduction to practice. Mr. Black’s affidavit states in material part:

- He was employed by Monsanto on October 14, 1968. He was assigned responsibility for the following areas:
  - Petroleum Additives
  - Functional Fluids
  - Polyphenyl Ethers

\(^3\) “Cavitation” may be defined as “Formation of gas or vapor-filled cavities within liquids by mechanical forces; **”; specifically, the formation of vapor-filled cavities in the interior or on the solid boundaries of vaporized liquids in motion where the pressure is reduced to a critical value without a change in ambient temperature.” *McGraw-Hill Dictionary of Scientific and Technical Terms* 237 (1974).
Synthetic Lubricants

• He was assigned four areas because the three attorneys who had previously handled them had resigned in the previous four months.

• He recalls that as of January 1969 he was responsible for:
  1) about 60 to 70 pending U.S. Applications
  2) over 400 foreign pending applications
  3) over 100 active invention disclosures of which
     27 were A – ready to file
     21 were A – not ready to file

• He recalls that as of that date, [Miller’s] invention disclosure *** was in order of filing priority, 31st on the list out of 48 cases.

• He generally filed invention disclosures according to their order of priority.

The Board Opinions

The board majority found that Miller had actually reduced the invention of the counts to practice in April 1966 and that he had not abandoned, suppressed, or concealed the invention within the meaning of 35 U.S.C. § 102(g). The majority found that Miller’s March 1966 vibrating probe tests were sufficient to show that the invention was suitable for the use set forth in the counts, i.e., cavitation inhibition in hydraulic systems. The tests were held not to have been abandoned experiments. The majority rejected Peeler’s claim that Miller had suppressed the invention, on the basis that there was no evidence that Miller intended to suppress the invention or in fact did so.

The dissenting member disagreed on both the reduction to practice and suppression issues. He concluded that the single probe test using FREON 11 as the additive was insufficient to establish reproducibility of results, citing Conner v. Joris, 241 F.2d 944 (CCPA 1957), and that Miller’s March 14 notebook entry showed that Miller believed he had a “lead,” not an actual reduction to practice, which required further experimentation “to better assess such additives.” The dissenter viewed the inactivity at Monsanto after the purported reduction to practice, coupled with Stainbrook’s 1967 experiments, to indicate a lack of conviction of success by those in authority at Monsanto, and he concluded that the March 1966 tests constituted abandoned experiments. On the suppression issue, the dissenter commented:

*** I also believe that the patent statutes were not designed to protect a first inventor who slumbers, to the detriment of a second inventor who tries to disclose his invention to the public and this I believe is what we have before us.

He concluded that the delay at Monsanto was “an unreasonable delay analogous to ‘res ipsa loquitur’ transferring the burden of proof to Miller to prove that the invention was not suppressed, concealed, or abandoned under the provisions of 35 USC 102(g).” The dissenter relied on the majority and concurring opinions—the latter by the author of this opinion—in Young v. Dworkin, 489 F.2d 1277 (CCPA 1974), to support this conclusion.
Opinion

While we agree with the board majority that Miller proved by a preponderance of the evidence that he had actually reduced the invention to practice in March 1966, we also agree with the dissenting member of the board that Miller must be deemed to have suppressed the invention under 35 U.S.C. § 102(g) through the behavior of his assignee. Perforce, the decision of the board must be reversed. We reach both issues, since without an actual reduction to practice there is no invention in existence which can be abandoned, suppressed, or concealed under § 102(g). Bogoslowsky v. Huse, 142 F.2d 75 (CCPA 1944).

I

Peeler argues that the one successful vibrating probe test relied upon by Miller to establish an actual reduction to practice was preliminary in nature and failed to show that the invention would work “as intended to work in its practical contemplated use, i.e., as an aircraft hydraulic fluid ***.” Peeler also urges us to find that a single successful test is insufficient to establish reproducibility of results and that the probe test was an abandoned experiment because Miller lacked conviction of success. Connected with these arguments is Peeler’s contention that Miller is attempting to prove actual reduction to practice nunc pro tunc by relying on an affidavit by his colleague Fairing which, Peeler submits, presents Fairing’s opinion as of 1973, when it was executed, and not at the time of Miller’s reduction to practice in March 1966.

We note that the counts are not directed to aircraft hydraulic systems, which are special environments with high speed flow and extremes of temperature and pressure causing accelerated wear of valves and other hydraulic system components, but to hydraulic systems generally. Thus Miller need show only that his invention is suitable for reducing cavitation damage in any hydraulic system. We find Peeler in a peculiarly unfavorable position to assert that the vibrating probe test is insufficient to prove actual reduction to practice. The only tests disclosed in Peeler’s examples illustrating his invention are probe tests, and it is these tests upon which Peeler is in effect relying to show a constructive reduction to practice by the application which matured into his patent. Miller’s March 14 notebook entry and the 1971 Monsanto brochure on “Aircraft Valve Life” do not suffice to show that the vibrating probe test was inadequate to demonstrate suitability of the Freon 11 additive for reducing cavitation damage in hydraulic systems generally. The Monsanto brochure is specifically addressed to testing additives for use in aircraft. Thus, it may be true that the vibrating probe test is a rapid screening method for choosing candidates for more rigorous testing, but that does not vitiate the conclusion by Miller, corroborated by Fairing, that the vibrating probe test was considered in 1966 by those in the art, based in part on the knowledge that the success of water as an additive was predicted by the probe test, to simulate conditions which would cause valve damage in aircraft. This is more than ample nexus between the test conditions and the intended functional setting contemplated by the counts. Stencel v. Nordine, 481 F.2d 916 (CCPA 1973). Miller’s comment in the March 14 notebook entry indicating a need “to better assess such additives” does not, it seems to us, indicate that he considered Freon 11 unsuitable. In the same notebook entry Miller also said:
Low boiling additives have generally exhibited marked damage-reducing tendencies in the ultrasonic probe tests, even though no special precautions were taken to prevent loss of volatiles. Thus, hermetically sealed containers were not necessary for successful probe tests, and Miller knew it. Miller is not required to prove that Freon 11 was known by him to be a commercially practicable additive for use in aircraft in order to establish an actual reduction to practice. Miller's record, unrebutted by Peeler, suffices to show that the vibrating probe test was an adequate means for determining the suitability of Freon 11 as a cavitation damage reducing additive. Peeler has adduced no evidence to show that other tests are necessary. See Campbell v. Wettstein, 476 F.2d 642, 647 (CCPA 1973).

We are not disposed to hold that the single probe test was insufficient to show reproducibility of results. This invention is not in a notoriously unpredictable field like catalytic chemistry. The prior experience with water as an additive created confidence in the efficacy of the probe test. On the basis of all the evidence and the relative simplicity of the invention, see Patterson v. Hauck, 341 F.2d 131 (CCPA 1965), we find unpersuasive Peeler's argument that a series of probe tests was necessary to establish an actual reduction to practice. ... In this case the evidence supports by at least a preponderance the conclusion that a single probe test, consisting of a control run and a run with additive in the fluid, is sufficient to demonstrate to a reasonable certainty whether a particular additive will reduce cavitation damage in a hydraulic system. Peeler had ample opportunity to submit rebuttal evidence but failed to do so, placing his faith in the arguments of counsel, which are not evidence. In re Scarbrough, 500 F.2d 560 (CCPA 1974).

The Fairing affidavit and other evidence also lead us to conclude that Miller does not seek to establish actual reduction to practice nunc pro tunc, which this court held was impossible in Langer v. Kaufman, 465 F.2d 915 (CCPA 1972), and Heard v. Burton, 333 F.2d 239 (CCPA 1964). At the time of the work relied upon by Miller to prove actual reduction to practice, Miller's notebook entry indicates that Miller recognized that Freon 11 would work. The notebook entry is signed by Miller and witnessed by one Wygant, whose affidavit stating that he read and understood the notebook page on April 5, the day Miller filed his invention disclosure, is of record. ... This situation is not like those in Langer and Heard, where the evidence showed that while the unsuccessful appellants had in fact practiced the inventions there in issue, there was no evidence of contemporaneous appreciation of what had been done. The record is clear in this case that Miller recognized the success of Freon 11, and that persons of ordinary skill in the art would have recognized Freon 11 as a success, from the probe test results. See Spero v. Ringold, 377 F.2d 652 (CCPA 1967).

Finally, we hold that the March 1966 probe test was not an abandoned experiment. Except for Miller's September 1966 presentation, the record is devoid of any activity with respect to the invention by Miller personally after he filed the invention disclosure. This lack of activity is understandable in light of the realities of corporate research. Once he filed his invention disclosure with his superiors, Miller was finished with the invention. He had other work to do. If Monsanto desired protection
for its employee’s invention, any further action was in the hands of people other than Miller. That Stainbrook performed tests in 1967 on additives which the dissenting board member said were outside the scope of the counts is of no moment. There is no evidence that Miller changed his mind about the efficacy of the additives he found. In some cases the passage of a long period between reduction to practice and filing raises an inference that the purported reduction to practice was an abandoned experiment. See, e.g., Bowers v. Valley, 149 F.2d 284 (CCPA 1945). This inference, however, only arises where there is doubt that the activities relied on constitute a reduction to practice. Walkup v. Greig, 332 F.2d 800 (CCPA 1964). We have no reason to doubt that Miller considered his invention successful when he filed his invention disclosure; subsequent corporate inactivity does not raise the inference that Miller later thought his work incomplete or unsuccessful. As indicated below, this passage of time redounds to the detriment of Monsanto, but not because of an inference that there was no reduction of the invention to practice.

II

Determining whether a de facto first inventor, Miller in this case, should also be considered the de jure first inventor under § 102 requires resolution of the policy question: which of the rival inventors has the greater right to a patent? Brokaw v. Vogel, 429 F.2d 476 (CCPA 1970). Under the facts of this case and the public policy inherent in § 102(g), we hold that the evidence has raised an inference of suppression of the invention by Miller’s assignee, Monsanto, the real party in interest, which has not been rebutted. Monsanto’s conduct is, of course, imputable to Miller under elementary legal principles. In re Clark, 522 F.2d 623 (CCPA 1975); Wilson v. Goldmark, 172 F.2d 575 (CCPA 1949).

The evidence here is striking in its paucity. There is no evidence that Miller (or Monsanto) was spurred into filing his application by knowledge of Peeler’s invention; spurring, however, is not an essential element of suppression. Neither Miller nor anyone else at Monsanto appears to have had any specific intent to suppress or conceal the invention. But proof of specific intent to suppress is not necessary where the time between actual reduction to practice and filing is unreasonable. This unreasonable delay may raise an inference of intent to suppress. Pingree v. Hull, 518 F.2d 624 (CCPA 1975); Young v. Dworkin, 489 F.2d at 1281 n.3. The evidence shows, however, that over four years elapsed between the rating of Miller’s invention disclosure “A (Ready)” and Miller’s filing date and that much, if not all, of the delay occurred while the disclosure lay dormant in Monsanto’s patent department.

In our opinion, a four-year delay from the time an inventor is satisfied with his invention and completes his work on it and the time his assignee-employer files a patent application is, prima facie, unreasonably long in an interference with a party who filed first. The circumstances surrounding the delay and Monsanto’s attempted justification thereof serve only to persuade us of the correctness of our opinion. We make no criticism of Mr. Black; getting Miller’s application filed in the time he did may have been an extraordinary effort. Monsanto, however, can take no comfort in that, since its neglect of Miller’s application for the 2½ years preceding Mr. Black’s
arrival and its failure to replace two of the three attorneys who resigned were at least partial causes of the backlog which greeted Mr. Black.\textsuperscript{8}

In its brief, Monsanto attempts to justify its inaction as follows:

Although delay in filing was encountered as set forth in the affidavit of William T. Black *** the invention disclosure was handled in accordance with established Monsanto practices which is [sic] consistent with normal business practices. At the invention disclosure review meetings, which were conducted approximately semi-annually, Dr. Miller, and his immediate superior, Dr. Richard, consistently urged that a patent application be filed. The fact that the invention disclosure rating was never changed from “A – Ready to file” is indicative of the fact that Miller intended to get an application on file as soon as his patent attorney could do so.

This excuse is lame on two counts: First, there is no evidence of what Monsanto’s “established practices” were or that the review meetings ever took place. We will not accept statements in briefs as substitutes for evidence. Second, and more importantly, assuming the truth of Monsanto’s assertions, we do not consider this four-year delay to be in accordance with any “normal” business practice that we should accept as part of a sound patent system.\textsuperscript{9} Whether Monsanto’s behavior is, in fact, a normal business practice is immaterial. Concepts of normality in business, and in patent law, change; that a practice is normal does not mean that it is one that courts should approve. We certainly cannot approve of the supine attitude toward delay exhibited by the statement in Monsanto’s excuse that the “delay in filing was encountered,” as though it had been come upon by surprise. The record, however, contains nothing to show that the delay was other than fully within Monsanto’s control at all times.

Miller and the board majority rely heavily on the statement, often repeated in varying language by this court, that “Mere delay, without more, is not sufficient to establish suppression or concealment.” Young v. Dworkin, 489 F.2d at 1281, and cases cited therein. What we are deciding here is that Monsanto’s delay is not “mere delay” and that Monsanto’s justification for the delay is inadequate to overcome the inference of suppression created by its excessive delay. Surely, the word “mere” does not imply a total absence of a limit on the duration of the delay. ... As Mr. Justice Holmes said in Towne v. Eisner, 245 U.S. 418, 425 (1918), “A word is not a crystal, transparent and unchanged, it is the skin of a living thought and may vary greatly in color and content according to the circumstances and the time in which it is used.” The living thought clothed by the phrase “mere delay” is not susceptible of discernment as an absolute matter. Whether any delay is “mere” in contemplation of

\textsuperscript{8} It is appropriate to wonder why, if Mr. Black could get to and file Miller’s application in approximately 15 months, the three attorneys whom he replaced could not have completed it in much less time after it was marked ‘A – Ready’ in April 1966.

\textsuperscript{9} Furthermore, we cannot believe that anyone, let alone a sophisticated corporation like Monsanto, would consider letting four years pass as a normal or prudent business practice, in light of the encouragement to early filing inherent in 35 U.S.C. § 102(b), for example.
law is a policy decision that can be made only on a case-by-case basis. A delay may be of no legal consequence because it is not long enough. Or the delay may be excused by activities of the inventor or his assignee during the delay period. See, e.g., Frey v. Wagner, 87 F.2d 212 (CCPA 1937). There may be other factors. But as we intimated in Pingree v. Hull, in line with our warning in Young v. Dworkin, that “one who delays filing his application does so at the peril of a finding of suppression or concealment due to the circumstances surrounding the delay,” the unreasonable length of a delay may be ample circumstance in itself to find suppression. At least since Mason v. Hepburn, 13 App. D.C. 86 (1898), the courts have implemented a public policy favoring, in interference situations, the party who expeditiously starts his invention on the path to public disclosure through the issuance of patents by filing a patent application. This policy is now implemented through § 102(g) even as it was in Mason v. Hepburn prior to that statute, by denying de jure first inventor status to de facto first inventors who, or whose assignees, frustrate this policy.

We conclude that Monsanto’s delay was not “mere delay,” that the delay was excessive, and that as between Peeler and Miller, Peeler has the better right to a patent, on the statutory ground that Miller, through the acts of his assignee, suppressed the invention. The decision of the board is reversed.

Miller, Judge, concurring:

I agree that appellee reduced the invention to practice and that, through the acts of his assignee, he suppressed the invention. Under 35 U.S.C. § 102(g), a second inventor is not entitled to a patent unless the first inventor abandoned, suppressed, or concealed the invention. In an interference the burden of proving abandonment, suppression, or concealment falls on the second inventor, regardless of who filed first. Young v. Dworkin, 489 F.2d 1277, 1279 (CCPA 1974).

This court has consistently held that suppression or concealment, to amount to forfeiture of the right to a patent in favor of a later inventor, must be deliberate or intentional. Pingree v. Hull, 518 F.2d 624, 629 (CCPA 1975); Young v. Dworkin, 489 F.2d at 1280-81. Young v. Dworkin, however, was a harbinger of the outcome of this case. It was not redundancy when, speaking for the majority of this court, I wrote “Mere delay, without more, is not sufficient to establish suppression or concealment.” Mere delay is to be contrasted with excessive or unreasonable delay, which, without more, is sufficient to establish suppression or concealment. The four-year delay in this case, without more, is excessive.

Such delay, however, only gives rise to an inference of intent to suppress. Young v. Dworkin, 489 F.2d at 1281 n.3. It shifts the burden to the first inventor to explain the delay by showing that there was no intent to suppress. Appellee has failed to do so since he has presented virtually no evidence covering the 2½ year gap between reduction to practice and the arrival of attorney Black. This failure decides the case.

The majority indulges in dictum which would engraft onto the statute a policy “favoring *** the party who expeditiously starts his invention on the path to public disclosure *** by filing a patent application.” It implies that the failure to hire a sufficient number of attorneys to deal with a backlog of patent applications results in
forfeiture of the patent right to one who has been “expeditious.” However, not even diligence is required after reduction to practice.

The public policy referred to in Brokaw v. Vogel, 429 F.2d 476, 480 (CCPA 1970), is that prescribed by Congress in § 102(g). The party with the right to a patent is the first inventor unless he has abandoned, suppressed, or concealed the invention. The policy is concerned with the action or inaction of the first inventor—not that of his opponent. …

…

**Brown v. Barbacid**

276 F.3d 1327 (Fed. Cir. 2002)

Rader, Judge:

In an interference over a new assay to identify anti-cancer compounds, the United States Patent and Trademark Office Board of Patent Appeals and Interferences (Board) awarded priority to Mariano Barbacid and Veeraswamy Manne (collectively Barbacid) over Michael Brown, Joseph Goldstein, and Yuval Reiss (collectively Brown). Because the Board did not consider evidence that Brown conceived the invention before Barbacid reduced it to practice and diligently pursued the invention from the time of Barbacid’s reduction to practice through Brown’s filing date, this court vacates the award of priority to Barbacid and remands.

**Background**

This case involves an interference between U.S. Patent No. 5,185,248 (the Barbacid patent) and U.S. patent application Serial No. 07/937,893 (the Brown application). The Barbacid patent and the Brown application both claim an assay for identifying new anti-cancer compounds that inhibit farnesyl transferase (FT), an enzyme involved in the control of cell growth. FT functions in the cell by adding farnesyl … to a cysteine amino acid near one end of the protein chain … . An important protein susceptible to addition of farnesyl is “ras.” The farnesylation reaction activates the ras protein (which stimulates cell growth) by moving ras to the vicinity of the cell membrane. Once near the membrane, ras stimulates cell growth. Thus, an FT inhibitor would reduce the amount of ras reaching the membrane and therefore reduce ras-stimulated growth (including “cancerous” growth).

…

The Barbacid patent application was filed on May 8, 1990, and issued on February 9, 1993. The Brown application was filed on December 22, 1992, but was accorded the benefit of an earlier related application filed on April 18, 1990. Thus, Brown was the senior party. Barbacid, as the junior party, had the burden to prove priority by a preponderance of the evidence.

The Board found that Barbacid showed an actual reduction to practice no later than March 6, 1990. The Board also found that Brown did not show reduction to practice of the count before March 6, 1990. Specifically, the Board found that Dr. Yuval Reiss’ September 20, 1989 FT experiment did not satisfy every limitation of the count because it did not include a test or candidate substance in the assay. The Board also discounted a September 25, 1989 experiment (which may have satisfied
the count) because Dr. Reiss could not authenticate his lab notebooks and autoradiographs. Moreover Dr. Patrick Casey could not corroborate Dr. Reiss’ testimony and documents relating to the September 25 experiment.

Discussion

Priority and its issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings. Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Accordingly, this court reviews without deference the Board’s legal conclusions on priority, conception, and reduction to practice, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), and reviews for substantial evidence the Board’s factual findings. Dickinson v. Zurko, 527 U.S. 150 (1999); In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Finally this court reviews the Board’s application of its permissive interference rules for an abuse of discretion. Abrutyn v. Giovannello, 15 F.3d 1048, 1050 (Fed. Cir. 1994).

I.

In an interference with an application filed after the date of the patent, the junior party must show priority by clear and convincing evidence. 37 C.F.R. § 1.657(c) (2001); Price v. Symsek, 988 F.2d 1187, 1190-91 (Fed. Cir. 1993). In interferences, such as this case, with an application whose effective filing date antedates the patent issuance, the junior party must show priority by a preponderance of the evidence. 37 C.F.R. § 1.657(c); Bosies v. Benedict, 27 F.3d 539, 541-42 (Fed. Cir. 1994). Barbacid, as the junior party, has the ultimate burden to prove priority. Id. Brown asserts that the Board inappropriately shifted the burden of proof by requiring Brown to show by a preponderance conception or reduction to practice before March 6, 1990—the date of Barbacid’s actual reduction to practice. Brown argues that the Board should have shifted to Brown the burden of production—the burden of going forward with sufficient evidence—rather than the burden of proof.

This court has not addressed whether a senior party has the burden to show by a preponderance a date of invention before the priority date shown by the junior party. The Board cites to a Board decision, Fisher v. Gardiner, 215 USPQ 620, 625 (Bd. Pat. Interferences 1981) (“Inasmuch as Fisher et al. [the junior party] have established a reduction to practice of the subject matter in counts 1, 2 and 4 prior to the senior party’s filing date, the burden shifts to Aymami [the senior party] to prove by a preponderance of the evidence a priority date for that subject matter earlier than the July 12, 1973 date established by Fisher et al.”).

To the contrary, 37 C.F.R. § 1.657(a) states: “A rebuttable presumption shall exist that, as to each count, the inventors made their invention in the chronological order of their effective filing dates. The burden of proof shall be upon a party who contends otherwise.” (emphasis added). Paragraph (b) of the same section explains that the junior party has the burden of establishing priority by a preponderance of evidence. 37 C.F.R. § 1.657(b). In other words, the burden of proof by a preponderance of the evidence “shall be on a party” contending they made their invention
out of chronological order of the effective filing dates, i.e., the junior party. This burden of proof does not shift.

Irrespective of that burden, however, both parties must be given an opportunity to submit evidence regarding priority in an interference proceeding. Once all evidence has been submitted, the Board must assess, in light of all the evidence presented by both parties, whether the junior party has met its ultimate burden of proving priority by preponderance of the evidence.

In sum, under 37 C.F.R. § 1.657(a) and (b), the ultimate burden of proof always remained on the junior party, Barbacid. Thus, the Board erred in stating that the burden of proof shifted to Brown at any point in this case. Notwithstanding that error, this court must still determine whether the record supports the Board’s award of priority to Barbacid. Specifically, this court (or the Board on remand, as the case may be) must determine, based on the entire evidentiary record, whether Barbacid ultimately prevailed in proving priority by a preponderance of evidence.

II.

Brown alleges that the Board erred in denying authentication to Dr. Reiss' lab notebooks and autoradiographs under 37 C.F.R. § 1.671(f). Paragraph (f) of § 1.671 (entitled “Evidence must comply with rules”) states: “The significance of documentary and other exhibits identified by a witness in an affidavit or during oral deposition shall be discussed with particularity by a witness.” 37 C.F.R. § 1.671(f) (2001) (emphasis added). The Board noted that § 1.671(f) requires a witness to explain the entries of various pages of the lab notebooks and exhibits. Cf. Fed. R. Evid. 902 (excluding notes and lab notebooks from the list of self-authenticating extrinsic evidence). The Board found that Dr. Reiss did not give sufficient testimony regarding specific entries in his lab notebook or on relevant autoradiographs (i.e., Exhibit 32). Without an adequate explanation of Exhibit 32, the Board rejected the exhibit for lack of authentication.

Exhibit 32 refers to notebook pages and autoradiographs from Dr. Reiss’ experiments from August to October 1989, including experiments dated September 20 and September 25, 1989. With regard to the September 25 experiment, Dr. Reiss stated in paragraph 24 of his declaration:

On September 25, 1989, I conducted an assay to determine the pH dependence of the farnesyl transferase preparation currently under use (Exhibit 32; pages 0035 to 0039). This study employed a peptide considered to be a potential inhibitor of ras farnesylation. This peptide comprised the carboxy-terminus ten amino acids of the ras molecule. The format of this assay was the gel electrophoresis format, described above in paragraph 20 [discussing the September 20 experiment]. The radioautograph developed from the corresponding gel (Exhibit 32; page 0038) clearly shows that inclusion of peptide at 10 and 20 ìg (lanes 14 and 15, respectively) inhibited farnesyl transferase-mediated labeling of ras by 14C-FPP, as determined by the reduction/absence of ras-specific bands in these lanes.

This explanation informs one of skill in the art, upon a review of the relevant autoradiographs and lab notebook pages in Exhibit 32, that Dr. Reiss conducted an
FT experiment on September 20, 1989, and then conducted another FT assay using a peptide inhibitor on September 25, 1989. Moreover, an examination of the September 25 autoradiograph from those experiments, specifically lanes 14 and 15 (which can be identified by counting lanes starting from the left), shows that farnesyl transferase-mediated labeling of ras by $^{14}$C-FPP was reduced in the presence of the inhibiting peptide.

Dr. Reiss did not analyze every lane in the autoradiograph. For example, he did not expressly state which bands in the gels corresponded to the labeled ras protein. Nor did Dr. Reiss discuss the molecular weight markers (in lane 1 on the left of the autoradiograph). Likewise, he did not describe each experiment in every single lane of the gels. Nevertheless, comparing lanes 2-11 to lanes 14-15 in the September 25 autoradiograph, one of skill in this art would understand that Dr. Reiss had inhibited ras farnesylation in the presence of the peptide.

While Dr. Reiss could have discussed the September 25 experiment in more detail, the Board must nonetheless weigh that evidence from the vantage point of one of skill in the art. See Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996) (stating that the trier of fact can conclude for itself what documents show, aided by testimony about the meaning of the exhibit to one skilled in the art). In this case, the notebook data itself explains the methods and results of the September assays. Thus, in light of Dr. Reiss’ testimony, one of skill in this art would understand Exhibit 32 relating to the September experiments.

In excluding Exhibit 32 for lack of authentication, the Board applied its own rule. This court reviews the Board’s application of its rules for an abuse of discretion. Abrutyn, 15 F.3d at 1050. Notwithstanding that high standard of review, this court finds that the Board abused its discretion by excluding evidence within the understanding of skilled artisans when considering authentication requirements. See Mahurkar, 79 F.3d at 1578.

III.

Brown further argues that the Board erred in refusing to allow an inventor’s own documentation to corroborate his conception or reduction to practice. A party seeking to prove conception via the oral testimony of a putative inventor must proffer evidence corroborating that testimony. Singh v. Brake, 222 F.3d 1362, 1367 (Fed. Cir. 2000); Mahurkar, 79 F.3d at 1577; Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993). This corroboration rule does not apply with the same force to proof of inventive facts with physical exhibits. Mahurkar, 79 F.3d at 1577-78 (“This court does not require corroboration where a party seeks to prove conception through the use of physical exhibits. The trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art.”); Price, 988 F.2d at 1195-96; Loom Co. v. Higgins, 105 U.S. 580, 594 (1882).

Thus, Brown’s physical evidence, such as Dr. Reiss’ notebooks and autoradiographs, do not require corroboration to demonstrate the content of the physical evidence itself, namely that FT assay experiments took place on September 20 and 25, 1989. Conversely, however, the physical evidence in this case may not single-handedly corroborate Dr. Reiss’ testimony. See Price, 988 F.2d at 1195 (“Unlike a
situation where an inventor is proffering oral testimony attempting to remember specifically what was conceived and when it was conceived *** ‘corroboration’ is not necessary to establish what a physical exhibit before the board includes. Only the inventor’s testimony requires corroboration before it can be considered.”). Thus, an inventor’s testimonial assertions of inventive facts require corroboration by independent evidence. Thomson S.A. v. Quixote Corp., 166 F.3d 1172, 1174-75 (Fed. Cir. 1999).

This court applies a “rule of reason” analysis to determine sufficient corroboration. Singh, 222 F.3d at 1367; Price, 988 F.2d at 1195. In applying the “rule of reason” test, this court examines “all pertinent evidence” to determine the credibility of the “inventor’s story.” Price, 988 F.2d at 1195. This “rule of reason” analysis does not alter the requirement of corroboration for an inventor’s testimony. The inventive facts must not rest alone on testimonial evidence from the inventor himself. …

Thus, independent evidence must corroborate Dr. Reiss’ testimony of conception or actual reduction to practice. The Board did not err in holding that an inventor’s own unwitnessed documentation does not corroborate an inventor’s testimony about inventive facts.

IV.

Conception is “the formation in the mind of the inventor[] of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” Singh, 222 F.3d at 1367 (quoting Kridl v. McCormick, 105 F.3d 1446, 1449 (Fed. Cir. 1997). A conception must encompass all limitations of the claimed invention, see id., and “is complete only when the idea is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation,” Id. (quoting Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994)).

As correctly found by the Board, Dr. Reiss did not satisfy every limitation of the count when he conducted his FT assay experiment on September 20, 1989. The laboratory notebook and autoradiograph themselves show that the September 20 experiment did not include the use of a test/candidate substrate (i.e., an inhibitor of FT)—an element of the count. Likewise, in the only independent testimony corroborating Dr. Reiss’ experiments, Dr. Casey did not suggest that the September 20 experiment included an FT inhibitor. Thus, the physical and testimonial evidence regarding the September 20 experiment do not show conception or reduction to practice.

V.

Unlike the September 20 experiment, the September 25 experiment included a peptide inhibitor of FT in the FT assay. Thus, the September 25 experiment contained all of the limitations of the count. As discussed above, however, independent evidence (testimony or physical evidence from a source other than Dr. Reiss) must corroborate Dr. Reiss’ testimony to show an actual reduction to practice. In other words, Dr. Casey’s testimony, the only other relevant independent evidence available, must corroborate Dr. Reiss’ own statements and documents to show a reduc-
tion to practice on September 25, 1989. Cooper, 154 F.3d at 1330. Dr. Casey’s testimony could not corroborate Dr. Reiss’ testimony regarding the September 25 experiment, however, because Dr. Casey did not purport to witness the September 25 autoradiograph. Nor did Dr. Casey purport to discuss the September 25 experiment in particular with Dr. Reiss at any time.

In his declaration submitted to the Board, Dr. Casey stated:

8. On Thursday, September 14, 1989, Dr. Janice Buss came to Southwestern Medical School to present a seminar. I recall that within a week or so of that date, Dr. Reiss showed me the results of a study in which he had demonstrated farnesyl transferase activity in a gel-based assay. *** [Description of the experiment] I distinctly recall this study, as it was a very important showing. The notebook page shown in Exhibit 32 as page 0031 [dated September 20, 1989] is the experiment Dr. Reiss showed to me. ***

9. In the latter part of September, 1989, there was a major development in my own research project that consumed my efforts, and distracted me from the farnesyl transferase project, for about one month. I recall, however, that by at least about the end of October or the beginning of November, I was aware that Dr. Reiss had demonstrated that short peptides, derived from ras, inhibited farnesyl transferase in vitro in the gel-based assay described above.

Thus, Dr. Casey did not discuss the September 25 experiment in his declaration. Consequently, the Board did not err when it determined that evidence regarding the September 25, 1989 experiment did not show a reduction to practice.

On the other hand, the physical evidence itself — the September 25 lab notebook pages and autoradiographs — show that an experiment containing all elements of the count took place on that date. As discussed above, this physical evidence requires no further corroboration to demonstrate the content of the physical evidence itself. Mahurkar, 79 F.3d at 1577; Price, 988 F.2d at 1195-96. In addition, while Dr. Casey’s vague testimony does not corroborate Dr. Reiss’ testimony of an actual reduction to practice, Dr. Casey’s testimony certainly suggests that Dr. Reiss had the idea of combining the FT assay with the use of FT peptide inhibitors sometime before the end of October or the beginning of November 1989. Thus, Dr. Casey’s independent testimony corroborates Dr. Reiss’ testimony of a conception before November 1989.

In the Facts section of their brief to the Board, Brown stated that they conceived of the invention by September 25, 1989, when that assay showed both FT activity and an inhibition of FT activity by candidate inhibitors. Moreover, in their Argument section, under “Brown’s First Alternative Case for Priority—‘Simultaneous’ Conception and Reduction to Practice,” Brown argued (albeit in the alternative and primarily in the section title itself) that Brown both conceived and reduced to practice their invention on September 25, 1989. Brown also cited Dr. Reiss’ September 25 lab notebook pages and autoradiographs, as well as Dr. Casey’s independent corroboration of Dr. Reiss’ testimony regarding conception before the end of October or the beginning of November 1989.
Despite Brown’s argument and citation to relevant physical and testimonial evidence, the Board did not address whether the September 25 experiment demonstrated conception. The Board only addressed whether the September 20 experiment demonstrated conception and whether the September 25 experiment demonstrated an actual reduction to practice. Moreover, the Board noted: “Without a conception, the issue of reasonable diligence by the inventors to a reduction to practice is moot. Accordingly, we have not considered any evidence relating to diligence.”

Priority of invention “goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice.” Price, 988 F.2d at 1190. Because Brown asserted to the Board conception of the invention on September 25, and invoked physical evidence that did not require corroboration, as well as testimony by Dr. Casey corroborating Dr. Reiss’ testimony regarding conception, the Board erred in failing to consider whether the September 25 lab notebook pages and autoradiographs themselves, especially in light of the independent testimony by Dr. Casey, demonstrated conception by Brown. Likewise, the Board erred in failing to consider whether Brown was diligent from March 6, 1990, the date of Barbacid’s actual reduction to practice, until Brown’s filing date on April 18, 1990.

…

Conclusion

Because the Board did not consider the September 25, 1989 experiment or Dr. Casey’s corroborating testimony with regard to conception by Brown, or any evidence of reasonable diligence by Brown between the date of Barbacid’s actual reduction to practice and the filing of Brown’s patent application on April 18, 1990 …, this court vacates the award of priority to Barbacid. Accordingly, this court remands this case back to the Board for further proceedings on Brown’s conception and reasonable diligence.

Newman, Judge, dissenting:

… I must dissent from my colleagues’ assignment of error to the Board’s statement of the procedural burdens; this court’s departure from decades of precedent and practice is unwarranted.

…

I agree that the Board erred in law in its treatment of the proffered evidence of corroboration. Dr. Reiss’ testimonial and documentary evidence of conception and reduction to practice was supported by witnesses who testified variously that they conducted chemical and biological analyses, ordered and prepared materials, discussed the work in progress and its results, and repeated the work. The purpose of the corroboration requirement is to probe the veracity of the inventor’s assertions by determining, on the entirety of the testimonial and documentary record, whether it is more likely than not that the asserted activities and events occurred.

… A full record has been presented, of generally undisputed facts. … Applying the correct law to the undisputed facts with respect to conception, diligence, and
reduction to practice, it follows that the party Brown established priority of invention before the dates established by the party Barbacid.

**Brown v. Barbacid**

436 F.3d 1376 (Fed. Cir. 2006)

Newman, Judge:

This appeal ... returns to the Federal Circuit ... . The parties are Michael Brown, Joseph Goldstein and Yuval Reiss (together “Brown”) and Mariano Barbacid and Veeraswamy Manne (together “Barbacid”). The invention common to Brown and Barbacid is a method or assay for identifying compounds that inhibit farnesyl transferase (“FT”), an enzyme involved in the control of cell growth. ...

...  
In the first appeal, Brown I, this court held that the Board erred in holding, *inter alia*, that the laboratory notebooks and recorded autoradiographs of Dr. Yuval Reiss were inadequately explained on their face and therefore could not serve as evidence of either conception or reduction to practice. The Federal Circuit reversed, holding that the Board must “weigh that evidence from the vantage point of one of skill in the art,” Brown I, 276 F.3d at 1334, and that the testimony of Dr. Patrick Casey, taken with the content of the notebooks, was adequate to corroborate Dr. Reiss’ testimony as to conception of the invention, although Dr. Casey’s evidence was not sufficiently specific to serve as corroboration of an actual reduction to practice. The court stated that “while Dr. Casey’s vague testimony does not corroborate Dr. Reiss’ testimony of an actual reduction to practice, Dr. Casey’s testimony certainly suggests that Dr. Reiss had the idea of combining the FT assay with the use of FT peptide inhibitors sometime before the end of October or the beginning of November 1989.” Brown I, 276 F.3d at 1337. We remanded to the Board for more precise determination of the party Brown’s date of conception, and determination of Brown’s reasonable diligence, as the party who was first to conceive but second to reduce to practice.

On remand, the Board held that Brown had established conception no later than November 15, 1989, but had failed to provide corroborated evidence of diligence. The Board again awarded priority to Barbacid, and Brown again appeals.

Discussion

The party that is first to conceive the invention in interference, if last to reduce the invention to practice, is entitled to the patent based on prior conception if, as first to conceive, he exercised reasonable diligence from a time before the other party’s conception date to his own reduction to practice date. See 35 U.S.C. § 102(g); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996) (a party that is first to conceive but second to reduce to practice “must demonstrate reasonable diligence toward reduction to practice”).

The purpose of requiring reasonable diligence by the first to conceive the invention but second to reduce to practice is to assure that the invention was not abandoned or unreasonably delayed by the first inventor during the period after the second inventor entered the field. The question of reasonable diligence is one of
fact. In re Jolley, 308 F.3d 1317, 1329 (Fed. Cir. 2002); Scott v. Koyama, 281 F.3d 1243, 1246 (Fed. Cir. 2002). We review the Board’s factual findings for support by substantial evidence. See Dickinson v. Zurko, 527 U.S. 150, 155 (1999) (applying the criteria of the Administrative Procedure Act to review of rulings of the PTO). The admissibility of physical and testimonial evidence is determined in accordance with the Federal Rules of Evidence, which have been adopted by the Board, 37 C.F.R. § 1.671(b) (1998), as amplified by precedent directed to patent interference proceedings.

Barbacid argues that Brown must show diligence measured from the Barbacid date of conception, not Barbacid’s date of reduction to practice. The first Board decision found Barbacid’s date of actual reduction to practice; the Board did not decide Barbacid’s conception date. Barbacid, the junior party, had been accorded its date of actual reduction to practice of March 6, 1990. No earlier date was proposed to this court in Brown I. Thus this court instructed that on remand the Board should determine whether Brown showed reasonable diligence from March 6, 1990, until Brown’s filing date as constructive reduction to practice on April 18, 1990. Barbacid states that the Federal Circuit in Brown I erroneously limited the diligence inquiry to the period starting with Barbacid’s date of reduction to practice, rather than the date of Barbacid’s conception. See Mahurkar, 79 F.3d at 1578 (when the first to conceive is the last to reduce to practice, reasonable diligence must be shown from “a date just prior to the other party’s conception”). Brown responds that this objection was not preserved, for Barbacid’s brief in Brown I did not suggest its possible entitlement to an earlier date than the reduction to practice date awarded by the Board. Further, Barbacid filed no objection, such as a request for reconsideration or clarification, if Barbacid believed that this court had issued legally flawed instructions for the determination of diligence on remand to the Board. This court’s instruction that the Board should determine Brown’s diligence upon remand necessarily presupposed that Barbacid did not have a prior conception date, for diligence is only required for the party that is “first to conceive.” 35 U.S.C. § 102(g). Brown states that this silence by Barbacid was a waiver of the issue of the scope of the diligence showing. We agree. On the information before the court, and the silence throughout briefing, argument, and decision, we hold that Barbacid waived the issue of the length of the period during which diligence should be shown. The Board did not err in declining to open the issue on remand. Cf. Barrow v. Falck, 11 F.3d 729, 730 (7th Cir. 1993) (“An argument bypassed by the litigants, and therefore not presented in the court of appeals, may not be resurrected on remand and used as a reason to disregard the court of appeals’ decision”).

Brown provided evidence from inventor Dr. Reiss and laboratory technician Ms. Morgan concerning the exercise of reasonable diligence during the period from Barbacid’s accorded date to Brown’s filing date. Dr. Reiss stated that after September 1989 he worked on the farnesyl transferase project “on a daily basis.” For the period following Barbacid’s actual reduction to practice on March 6, 1990, Dr. Reiss stated that his experiments were directed at further characterizing the FT enzyme, improving the methodology for purifying the enzyme, and improving the overall performance of the assay. He stated that he performed studies to assess the
metal dependency of FT, evaluated gels with various affinity chromatography eluates, conducted a freeze-thaw study to determine the stability of FT, performed cyanide bromide cleavage of various FT fractions and examined the products of that cleavage, studied the effect of guanosine triphosphate binding on farnesylation, and studied the effect of peptide saturation on FT activity. He provided laboratory notebook pages recording this work.

The Board rejected Dr. Reiss’ testimony for lack of corroboration, and also observed that even if his notebook records showing this work were deemed to corroborate his testimony, they recorded work on only ten of the thirty-one days from March 6 to April 18, and thus were insufficient to establish reasonable diligence.

Precedent requires that an inventor’s testimony concerning his diligence be corroborated. See Jolley, 308 F.3d at 1328 (“corroboration is required to support an inventor’s testimony regarding his reasonable diligence in pursuit of the invention”). Corroboration is determined by application of a rule of reason, for “corroboration of every factual issue contested by the parties is not a requirement of law.” Jolley, 308 F.3d at 1328; see also Price v. Synseck, 988 F.2d 1187, 1196 (Fed. Cir. 1993) (“all of the evidence put forth” must be considered “as a whole, not individually” in evaluating whether the inventor’s testimony is credible).

Unlike the legal rigor of conception and reduction to practice, diligence and its corroboration may be shown by a variety of activities, as precedent illustrates. For example, in Lacotte v. Thomas, 758 F.2d 611, 613 (Fed. Cir. 1985), the testimony of the inventor and his notebook records were held adequately corroborated by his obtaining relevant supplies and the testimony of his associate. In Bey v. Kollonitsch, 806 F.2d 1024, 1030 (Fed. Cir. 1986), diligence was shown by an attorney’s work in preparing the patent application. In Scott v. Koyama, 281 F.3d at 1248, diligence was shown by efforts to locate a construction company capable of building a manufacturing plant for practicing the process on a large scale. In Jolley, 308 F.3d at 1327, diligence was shown by activity to obtain necessary supplies and laboratory glassware and by testing of related materials. The basic inquiry is whether, on all of the evidence, there was reasonably continuing activity to reduce the invention to practice. There is no rule requiring a specific kind of activity in determining whether the applicant was reasonably diligent in proceeding toward an actual or constructive reduction to practice.

Brown provided evidence of laboratory work during this period performed by Debra Morgan, a scientist working in the Brown laboratory, as evidence of diligence and as corroboration of Dr. Reiss’ testimony. Ms. Morgan declared that she was aware that Dr. Reiss “was working on *** the development of an assay for screening of potential inhibitors of this [FT] enzyme,” that she worked on the FT assay, and that she performed experiments designed by Dr. Reiss. Ms. Morgan stated that her work was to “screen various peptides for possible inhibitory effect on farnesyl transferase.” She stated that the studies used a fiber-binding assay format where “farnesyl transferase, H-Fpp, ras substrate and the candidate inhibitor peptide were incubated together,” and that the methodology of the assay was that “when the radioactively labeled FPP is incorporated into the ras substrate, the radioactivity will associate with the filter by virtue of the adsorption of the ras thereto.” Ms. Morgan de-
scribed various farnesyl transferase inhibition studies with reference to the specific study numbers on the notebook pages, and the dates the work was done. She explained a comparative study, with reference to study number and date, in which “a biotin conjugated substrate is used rather than ras as a target for farnesylation,” as well as a study in which farnesyl transferase reaction samples were prepared for analysis by thin layer chromatography. Her declaration was accompanied by copies of thirty-eight laboratory notebook pages. Each of the thirty-eight notebook pages was associated with tests specified in her declaration.

The Board found that Ms. Morgan’s notebook records along with those of Dr. Reiss filled all but six days of the critical period, and that each of the six remaining days was a single-day gap; this was deemed sufficient to show substantially continuing activity. The Board found that Ms. Morgan “worked for the inventors” and that “her work could inure to the benefit of the inventors to establish reasonable diligence over the entire period.” However, the Board refused to credit any of Ms. Morgan’s evidence, criticizing what it described as the absence of explanation of the content and purpose of these experiments. The Board stated that it was not clear from the face of the notebook pages what Ms. Morgan had done and why, presenting as an example of an inadequate record the following page of Ms. Morgan’s notebook[.]
The Board stated that it “surmised” that this page recorded 11 experiments involving the ras oncogene protein, farnesyl pyrophosphate, and a peptide, based on the designations “RAS,” “FPP” and “Peptide # 3” in the column headings. The Board described its concerns as follows:

the relationship between ras, farnesyl pyrophosphate and peptide is not explained. Nor are the results of the assays understood. What do they signify?  

*** The issue is whether Ms. Morgan’s work shows reasonable diligence was exercised to reduce the invention of the count to practice. We are given a number of laboratory pages, the content of which is never explained, leaving it to us to decipher whether they are relevant and to what extent they are relevant to the issue of reasonable diligence. There is no explanation of what these pages are saying.

The Board also stated that if Ms. Morgan’s evidence were credited, it would suffice, with that of Dr. Reiss, to establish diligence.

Brown states that Ms. Morgan’s work was explained in her declaration, and that her notebook pages report the subject of her studies in scientific detail that would be readily understood by persons experienced in this field. Brown points out that her declaration references specific study numbers recorded on the notebook pages and the dates recorded on those pages, and that her declaration and documentary records would be understood by persons experienced in this field of science. Brown states that the Board erred in requiring that the records themselves and the content of the supporting declaration contain explanations more elaborate than needed to record the work and communicate to persons experienced in this field. Barbacid defends the Board’s ruling, characterizing Ms. Morgan’s testimony as “cursory” and fatally flawed because it did not explain how each experiment moved the inventive process toward completion, and states that the Board acted reasonably in refusing to credit any of Ms. Morgan’s evidence as showing reasonable diligence and establishing corroboration of Dr. Reiss’ testimony.

We conclude that the Board erred in law, in failing to view the proffered evidence as it would be viewed by persons experienced in the field of the invention. See *Mahurkar*, 79 F.3d at 1577-78 (the trier of fact is aided by an understanding of how the evidence would be viewed by one skilled in the art). The Board is charged with expertise appropriate to the invention under examination, and with understanding that a laboratory notebook recording daily experimentation, reasonably considered from the viewpoint of persons experienced in the field, need not reproduce on each page a statement of the larger research purpose; this purpose may reasonably be shown in the various declarations.

It is undisputed that the subject matter recorded on the Morgan notebook pages and described in her declaration concerns the subject matter of the count. This is the same form and content of evidence that the court in *Brown I* deemed admissible for purposes of showing conception. The Board agreed that Ms. Morgan’s activity during the critical period, if accepted into evidence, established diligence. We conclude that the Board erred in refusing to accept this evidence, and that reasonable diligence is deemed established.
The Board’s holding that Brown’s reasonable diligence had not been shown is reversed. The only remaining issue of which we have been made aware relates to patentability. The Board did not review the ruling of the administrative patent judge denying Barbacid’s motion challenging the patentability of Brown’s claims, deeming this aspect “moot” because of the award of priority to Barbacid. Brown asks us to take up this issue “in the interests of judicial economy,” expressing concern about the time already consumed in this interference proceeding and the delay of a further remand. Indeed, this interference has been pending for over ten years. However, we must agree with Barbacid that the question of patentability cannot be decided ab initio on appeal. See In re Lee, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (“review of an administrative decision must be made on the grounds relied on by the agency”). Although we deplore the lengthy pendency of this proceeding, on remand the Board may decide whether further proceedings as to this issue are warranted.

Editor’s Note:

Apotex USA, Inc. v. Merck & Co.
254 F.3d 1031 (Fed. Cir. 2001)

Lourie, Judge:
Apotex USA, Inc. appeals from the decision ... granting Merck & Co., Inc.’s motion for summary judgment that the claims of U.S. Patents 5,573,780 and 5,690,962 are invalid under 35 U.S.C. § 102(g). Because the district court did not err in granting summary judgment that the ’780 and ’962 patents are invalid under 35 U.S.C. § 102(g), we affirm.

Background
Apotex is the assignee of the ’780 and ’962 patents, which relate to a process for making a stable solid formulation of enalapril sodium for use in the treatment of high blood pressure. Claim 1 of the ’780 patent, which is representative of the claims at issue, reads as follows:

1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
   i) a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
   b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of an alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water,
   ii) drying the wet mass, and
iii) further processing the dried material into tablets.

The claims of the ’962 patent, which is a continuation of the application that led to the ’780 patent, are identical to those found in the ’780 patent except that they are not restricted to tablet form, but rather encompass any solid pharmaceutical dosage form of enalapril sodium. This distinction is not material to the resolution of this appeal.

Merck manufactures enalapril sodium under the trade name Vasotec, and has been continuously manufacturing and commercially selling Vasotec tablets since 1983. Merck owns both U.S. and Canadian patents covering the enalapril sodium compound, but does not own a patent covering its process of manufacturing Vasotec. However, in 1992, Merck disclosed the ingredients utilized in its Vasotec manufacturing process in a Canadian product monograph, and more than 30,000 copies of the monograph were distributed in 1993 alone. Merck also disclosed the ingredients used in manufacturing Renitec (the trademark used for its enalapril sodium product sold in various foreign countries) in the 1988 edition of the *Dictionnaire Vidal*, a French pharmaceutical dictionary.

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex’s Canadian affiliate, Apotex Canada, for infringement of Merck’s Canadian patent covering the enalapril sodium compound. During the 1994 trial (“the Canadian trial”), Brian McLeod, Merck’s then-vice president of marketing, performed a step-by-step narration of a videotape demonstrating Merck’s process of manufacturing Vasotec. Within days of hearing this testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue.

Apotex filed the present action against Merck, alleging that Merck’s process of manufacturing Vasotec infringes all of the claims of both the ’780 and ’962 patents. Both parties filed cross-motions for summary judgment on the issue of infringement, and Merck cross-moved for summary judgment of invalidity under § 102(g). The district court granted Apotex’s motion for summary judgment of infringement, but also granted Merck’s cross-motion for summary judgment of invalidity because it found that Merck invented the process claimed in the ’780 and ’962 patents within the United States before Apotex, and did not abandon, suppress, or conceal that invention within the meaning of § 102(g).

Apotex thereafter filed a motion asking the court to reconsider its grant of summary judgment of invalidity, which the district court denied. Apotex appeals from the district court’s grant of summary judgment of invalidity. ...

Discussion ...

Apotex argues that the district court improperly invalidated the ’780 and ’962 patents because Merck failed to prove by clear and convincing evidence that it did not suppress or conceal the patented process. Apotex contends that proof of invalidity under § 102(g) requires Merck to prove that it did not suppress or conceal the process of manufacturing Vasotec tablets based on its activities within the United States, and that Merck’s foreign disclosures therefore cannot be used to satisfy its burden of proof. Apotex also contends that, in any event, Merck’s foreign disclo-
sures fail to prove that it did not suppress or conceal the process because nothing in the testimony from the Canadian trial, the product monograph, or the French dictionary disclosed the use of water, the occurrence of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate, or the resultant enalapril sodium product. Finally, Apotex argues that the evidence demonstrates that Merck in fact suppressed or concealed its invention by failing to file a patent application on the process, by submitting misleading information in its New Drug Application (“NDA”) that only disclosed the starting ingredients used to make Vasotec, and by preventing the details of its process from circulating outside of the company.

Merck responds that § 102(g) only requires proof that the prior invention was made in the United States, and that evidence of lack of suppression or concealment can be proven by both foreign and domestic activities. Merck further argues that it did not suppress or conceal the process because it used it commercially, disclosed it in open court directly to its competitor, and published the ingredients used to make Vasotec tablets in both the product monograph and the French dictionary. Merck also argues that the submissions it made with respect to its NDA were proper and in any event could not constitute suppression or concealment because it was the Food and Drug Administration that never made those submissions public. Finally, Merck contends that the process was not suppressed or concealed because it was obvious and Dr. Sherman admitted that Vasotec tablets could be reverse-engineered to reveal the details of the process.

Section 102(g) operates to ensure that a patent is awarded only to the “first” inventor in law. In addition to governing priority determinations in interference proceedings in the PTO, § 102(g) may be asserted as a basis for invalidating a patent in defense to an infringement suit. New Idea Farm Equip. Corp. v. Sperry Corp., 916 F.2d 1561, 1566 (Fed. Cir. 1990). That section provides in relevant part that: “A person shall be entitled to a patent unless *** before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.” 35 U.S.C.A. § 102(g). Therefore, if a patentee’s invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent. New Idea, 916 F.2d at 1566.

Apotex does not dispute that Merck invented the patented process in the United States well before Dr. Sherman’s alleged date of conception. Apotex also concedes that Merck did not abandon its process of manufacturing Vasotec tablets as shown by its continuous commercial use of the process since 1983. The sole issue on appeal, therefore, is whether Merck “suppressed” or “concealed” the process within the meaning of § 102(g). Whether suppression or concealment has occurred is a question of law, which we review de novo. Brokaw v. Vogel, 429 F.2d 476, 480 (CCPA 1970).

As an initial matter, we disagree with Apotex’s interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made “in this country.” However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to interpret
the language “in this country” to also modify the requirement that the prior invention was “not *** abandoned, suppressed, or concealed.” A more reasonable interpretation is that it only modifies the antecedent verb “made,” but not the “abandoned, suppressed, or concealed” clause that follows it. Had Congress intended the phrase “in this country” to modify “abandoned, suppressed, or concealed,” it would have inserted language to that effect.

Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that precise modification, as it applied to another clause in § 102(g), and failed to adopt it. An earlier version of that provision considered in the House read as follows:

[B]efore the applicant’s invention thereof the invention was in fact made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice.

H.R. 3760, 82nd Cong. (1951) (emphasis added). The fact that the drafters found it desirable to emphasize that the language “in this country” applies to “using reasonable diligence” as well as to the word “made” supports the conclusion that it only modifies the verb that precedes it and not any subordinate clause that follows it. Accordingly, based upon the plain language of § 102(g) and the relevant legislative history of that provision, we conclude that the language “in this country” only applies to the country where “the invention was made,” and that proof negating suppression or concealment is not limited to activities occurring within the United States.

We next turn to an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense to an infringement suit under § 102(g)—the burdens of proof governing such a determination. Section 282 of the Patent Act provides that “[a] patent shall be presumed valid.” 35 U.S.C. § 282. In order to overcome the presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984). Section 282 applies with full force to a § 102(g) defense, and thus a party asserting invalidity under § 102(g) must prove facts by clear and convincing evidence establishing a prior invention that was not abandoned, suppressed, or concealed. See Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 915 (Fed. Cir. 1992).

In Young v. Dworkin, one of our predecessor courts set forth the relevant burdens of proof governing a determination whether a prior invention was suppressed or concealed, in the context of an interference between co-pending applications, as follows:

The sole remaining question is whether the board correctly held that junior party-appellant suppressed or concealed his invention within the meaning of 35 U.S.C. § 102(g). Here, the senior party-appellee bears the burden of proof by a preponderance of the evidence, notwithstanding junior party-appellant’s burden on the issue of priority of invention which he has sustained.
Young v. Dworkin, 489 F.2d 1277, 1279 (CCPA 1974). Thus, under § 102(g) interference law involving co-pending applications, once the first party to invent has established priority of invention, the second party to conceive and reduce the invention to practice has the burden of proving that the first party suppressed or concealed the invention. In such an interference, the first party to invent does not bear any burden of proof regarding suppression or concealment once it has established an earlier date of invention.

A § 102(g) prior invention defense is governed by the identical “suppressed or concealed” language applicable to priority determinations in interference proceedings. 35 U.S.C. § 102(g). We must therefore interpret the § 102(g) defense provision consistently with established interference law. However, infringement actions implicating a § 102(g) defense differ from interferences in that a patent has been granted on the invention at issue, and therefore the presumption of validity under § 282 applies.1 Because the patentee (analogous to the second-to-invent in the interference context) has the benefit of the presumption of validity, that party should only be held to bear a burden of producing evidence indicating that the prior inventor may have suppressed or concealed the invention once the challenger (analogous to the first-to-invent in the interference context) has established prior invention by clear and convincing evidence. That burden bears a rough similarity to placing the burden of proving suppression or concealment on the second-to-invent under interference law, but at the same time is appropriately limited to one of production, not persuasion, giving due regard to the presumption of validity.

We therefore interpret § 102(g) as requiring that once a challenger of a patent has proven by clear and convincing evidence that “the invention was made in this country by another inventor,” 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. However, in accordance with the statutory presumption in 35 U.S.C. § 282, the ultimate burden of persuasion remains with the party challenging the validity of the patent. See Innovative Scuba Concepts, Inc. v. Feder Indus., Inc., 26 F.3d 1112, 1115 (Fed. Cir. 1994) (“While a patentee may have the burden of going forward with rebuttal evidence once a challenger presented a prima facie case of invalidity, the

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1 Generally speaking, the presumption of validity does not apply to patents involved in interference proceedings, and thus the invalidity of a patent involved in an interference under § 102(g) need only be proven by preponderant evidence. See Bruning v. Hirose, 161 F.3d 681, 686 (Fed. Cir. 1998) (holding that, in an interference involving a patent issued from an application that was co-pending with the interfering application, the appropriate standard of proof for validity challenges is the preponderance of the evidence standard because the presumption of validity is inapplicable). However, the presumption may effectively be implicated in the case of a priority contest between an issued patent and an application that was filed after the issuance of the patent. In such a situation, the junior party must establish priority of invention by clear and convincing evidence. Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993). Such a factual scenario is not before us.
presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation.”). Once the patentee has satisfied its burden of production, the party alleging invalidity under § 102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary.

Our case law distinguishes between two types of suppression or concealment. The first is implicated in a situation in which an inventor actively suppresses or conceals his invention from the public. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996). The second involves a legal inference of suppression or concealment based upon an unreasonable delay in filing a patent application.2 *Peeler v. Miller*, 535 F.2d 647, 655 (CCPA 1976) (holding that a four-year delay in filing a patent application after the invention was perfected was unreasonably long); *Shindelar v. Holdeman*, 628 F.2d 1337, 1342 (CCPA 1980) (finding suppression or concealment because no reasonable explanation was given for the two-year and five-month delay between reduction to practice and the filing of a patent application). The latter type is involved here.

Although a prior inventor implicated in a § 102(g) infringement defense may not have filed a patent application, in contrast to an interference contestant, that party’s delay in otherwise bringing the knowledge of the invention to the public may nevertheless raise a similar inference of suppression or concealment. See *Int’l Glass Co. v. United States*, 408 F.2d 395, 403 (Ct. Cl. 1969) (holding that the prior invention of a process did not invalidate a patent on the same process under § 102(g) because the prior inventor did nothing to make the invention known to the public). Even though there is no explicit disclosure requirement in § 102(g), the spirit and policy of the patent laws encourage an inventor to take steps to ensure that “the public has gained knowledge of the invention which will insure its preservation in the public domain” or else run the risk of being dominated by the patent of another. *Palmer v. Dudzik*, 481 F.2d 1377, 1387 (CCPA 1973); see also *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1446 (Fed. Cir. 1984) (defining § 102 “prior art” to be “technology already available to the public,” and stating that “secret prior art” may not be used to invalidate a patent under § 102(g)); *Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997) (“[W]hen the possessor of secret prior art (art that has been abandoned, suppressed, or concealed) that predates the critical date is faced with a later-filed patent, the later-filed patent should not be invalidated in the face of this ‘prior’ art, which has not been made available to the public. Thus, prior, but non-public, inventors yield to later inventors who utilize the patent system.”). Absent a satisfactory explanation for the delay or the presence of other mitigating facts, a prior invention will therefore be deemed suppressed or concealed within the meaning of § 102(g) “if, within a reasonable

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2 A subset of the category of “inferred” suppression or concealment arises in a situation in which the first inventor is “spurred” into filing a patent application by another application, *Mason v. Hepburn*, 13 App. D.C. 86 (D.C. Cir. 1898), or by the commercial activity of another, *Woofter v. Carlson*, 367 F.2d 436, 445-446 (CCPA 1967). This case does not involve “spurring.”
time after completion, no steps are taken to make the invention publicly known.”  

*Int’l Glass*, 408 F.2d at 403.

In the case at hand, we find that Apotex has satisfied its burden of producing evidence sufficient to create a genuine issue of material fact that Merck suppressed or concealed its process of manufacturing enalapril sodium tablets. We emphasize at the outset that although § 102(g) prior art must be somehow made available to the public in order to defeat another patent, a § 102(g) prior inventor is under no obligation to file a patent application. *Checkpoint Sys., Inc. v. United States Int’l Trade Comm’n*, 54 F.3d 756, 763 (Fed. Cir. 1995). Thus, while Merck’s failure to file a patent application may be relevant to a determination whether it suppressed or concealed its process, especially if there were evidence that such failure was based on a decision to retain the invention as a trade secret, that failure alone does not satisfy the patentee’s burden of producing evidence sufficient to create a genuine issue of material fact of suppression or concealment. See *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir. 1988) (explaining that a patent application need not be filed on an invention for it to be considered § 102(g) prior art as long as the invention is found not to have been abandoned, suppressed, or concealed).

However, Apotex did allege that Merck failed to make its invention publicly known. Merck perfected its process and began commercially using the process to manufacture Vasotec tablets no later than 1983. Although Merck argues that its process was disclosed to the public because its Vasotec tablets could have been reverse-engineered, that argument is based on the admissions of Dr. Sherman, who drew upon the information provided in Merck’s subsequent disclosures to determine the details of the process.\(^3\) Thus, it appears that Merck took no steps to make the invention publicly known for nearly five years, when it first published the ingredients used in its process in the 1988 edition of the *Dictionnaire Vidal*. We find that such a delay raises an inference that Merck suppressed or concealed its invention. Accordingly, because Apotex has successfully discharged its burden of going forward with evidence creating a genuine issue of material fact of suppression or concealment, the burden shifts to Merck to rebut that showing by clear and convincing evidence to the contrary.

We conclude that Merck has succeeded in rebutting the inference of suppression or concealment created by its period of inactivity by clear and convincing evidence. In *Paulik v. Rizkalla*, we stated the rule that “the first inventor will not be barred from relying on later, resumed activity antedating an opponent’s entry into the field, merely because the work done before the delay was sufficient to amount to

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\(^3\) It is worth noting that if it were clear that Merck’s process could be reverse-engineered by one of ordinary skill through an inspection of Vasotec tablets, Apotex could not benefit from the inference of suppression or concealment because Merck could not be said to have delayed in making the benefits of its invention known to the public. See *Palmer*, 481 F.2d at 1386-87 (stating that a commercial use of an invention will preclude a finding of suppression or concealment only when such use enables the public to learn of the invention).
a reduction to practice.” 760 F.2d 1270, 1275 (Fed. Cir. 1985) (holding that the inference of suppression or concealment from a four-year delay between reduction to practice and the filing of a patent application was overcome by the first inventor’s resumption of activity before the second inventor’s date of conception). Thus, even though Merck may have suppressed or concealed the process for a period of time after it reduced it to practice in 1983, as long as it “resumed activity” (i.e., made the benefits of its invention known to the public) before Apotex’s entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).

Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex’s entry into the field (here, Dr. Sherman’s alleged conception in April of 1994). First, Merck disclosed the ingredients used in manufacturing Vasotec tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex argues that these disclosures inadequately described Merck’s process of manufacturing Vasotec tablets, and therefore that the public never received the benefit of the invention. However, Dr. Sherman admitted both in his deposition in this case and in his 1994 Statement of Facts prepared for the Canadian trial that his inspection of the Vasotec tablets that Merck sold commercially revealed that they were made using a wet granulation process. He also admitted that, after learning of the disclosed starting ingredients from the Canadian product monograph (which included sodium bicarbonate), it “immediately occurred” to him and was “obvious to any knowledgeable formulator or chemist” that the final enalapril sodium product in the Vasotec tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate in water. Merck’s various disclosures, in conjunction with Apotex’s admissions, therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex’s evidence of suppression or concealment.

Moreover, Apotex’s argument that Merck suppressed or concealed the process by submitting misleading information to the FDA in 1983 is irrelevant because any suppression that was implicated was overcome by Merck’s subsequent activity. We therefore conclude that the district court did not err in granting summary judgment that the ’780 and ’962 patents are invalid under § 102(g).

We have considered Apotex’s remaining arguments and find them to be unpersuasive.

...
Amkor Technology v. International Trade Commission
692 F.3d 1250 (Fed. Cir. 2012)

Linn, Judge:

Complainant-Appellant, Amkor Technology (“Amkor”), appeals the determination of the International Trade Commission (“Commission”) that Amkor’s U.S. Patent No. 6,433,277 is invalid under 35 U.S.C. § 102(g)(2). The respondents in the Commission investigation below, Carsem (M) Sdn Bhd, Carsem Semiconductor Sdn Bhd, and Carsem, Inc. (collectively, “Carsem”), intervene. Because the Commission applied an erroneous legal standard, this court reverses the Commission’s determination on prior invention under § 102(g)(2). …

I. Background


A. ’277 Patent

The ’277 Patent, titled “Plastic and Integrated Circuit Package and Method and Leadframe for Making the Package,” was filed on July 13, 2000, and issued on August 13, 2002. The invention relates to smaller and “more reliable” integrated circuit packages. Integrated circuit die—small blocks of semiconducting material that contain a circuit—are conventionally enclosed in a plastic package, or “encapsulant.” A metal leadframe serves as the central support structure for the package. In the prior art, part of the leadframe was completely surrounded by encapsulant, and part of the leadframe extended outside of the package to connect the package externally. The internal structure of the leadframes in the prior art limited the ability of those in the art to further reduce the package size.

The claimed packages are “near chipscale” packages, meaning that the finished package is only marginally larger than the semiconductor chip itself. The smaller size is achieved by encapsulating only a top portion of the package. Fig. 2 from the ’277 Patent depicts the invention:
B. Procedural History

On February 11, 2004, the Administrative Law Judge issued a subpoena to third parties ASAT, Inc., ASAT Holdings, and ASAT Limited (collectively, “ASAT”), seeking certain documents related to ASAT’s leadless plastic chip carrier package invention (“ASAT invention”) described in U.S. Patent 6,229,200 that Carsem asserted were critical to its defense. ASAT failed to comply with the subpoena. On November 18, 2004, prior to receiving the ASAT documents, the ALJ issued a first Initial Determination finding no violation of section 337. The ALJ determined (1) that some or all of Carsem’s accused micro leadframe package products infringed claims 1, 7, 17, and 20 of the ’277 Patent; (2) that claims 1, 7, 17, 18, and 20 of the ’277 Patent were invalid as anticipated; and (3) that claims 2-4 and 21-23 of the ’277 Patent were [invalid as] indefinite...

On review, the Commission modified the ALJ’s claim construction ... and remanded. On November 9, 2005, the ALJ issued a second Initial Determination finding, based on the Commission’s claim construction, that (1) some or all of Carsem’s micro leadframe package products infringed claims 2-4 and 21-23 of the ’277 Patent; (2) that claims 2-4 and 21-23 of the ’277 Patent are not invalid as anticipated or obvious; and (3) that Carsem violated section 337. The new claim construction did not change the ALJ’s finding that claims 1, 7, 17, 18, and 20 were invalid as anticipated.

On July 1, 2009, after the Commission finally obtained the ASAT documents (following two enforcement petitions in district court), the Commission remanded the Investigation to the ALJ to determine whether the ASAT invention qualified as prior art to the ’277 Patent under 35 U.S.C. § 102(g)(2). On October 30, 2009, the ALJ issued a first Supplemental Initial Determination finding that (1) the co-inventor of the ASAT invention conceived of the ASAT invention in a foreign country sometime during April or May; and (2) Amkor’s ’277 Patent technology was conceived sometime during May through August, or on December 10, of that same year. Accordingly, the ALJ concluded that the ASAT invention is not prior art under § 102(g)(2) because “Carsem [...] failed to prove by clear and convincing evidence that the April/May [...] date of invention [for the ASAT invention] *** is prior to the [May through August] date of invention accorded the asserted claims of the patents-in-suit.” On review, the Commission reversed and remanded, holding that the ASAT invention is § 102(g)(2) prior art because, under Oka v. Youssefeyeh, 849 F.2d 581, 584 (Fed. Cir. 1988), the earliest possible priority date of the ’227 Patent must be the last date in the range of dates, or December 10, which falls after the April/May date of invention for the ASAT invention. On remand, the ALJ issued a second Supplemental Initial Determination holding all disputed claims of the ’277 Patent invalid under § 102(g)(2) in view of the ASAT invention. Amkor appeals the Commission’s holding that the ASAT invention qualifies as § 102(g)(2) prior art. …

II. Discussion

A. Standard of Review

This court reviews the Commission’s legal determinations de novo and factual determinations for substantial evidence. Gemstar-TV Guide Int’l, Inc. v. Int’l Trade Comm’n, 383 F.3d 1352, 1360 (Fed. Cir. 2004). “Priority of an invention is a
question of law to be determined based upon underlying factual determinations.” 

B. 35 U.S.C. § 102(g)(2)

1. Domestic Disclosure Under Scott

The American Inventors Protection Act of 1999 divided § 102(g) into subsections (1) and (2), eliminating the “made in this country” requirement under subsection (1) governing interferences, and retaining the “made in this country” requirement under subsection (2) governing prior invention generally. The post-AIPA version of § 102(g), which governs this appeal, provides in pertinent part:

A person shall be entitled to a patent unless:

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes *** that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it *** .

35 U.S.C. § 102(g) (emphasis added). Prior to the passage of the AIPA, § 102(g) did not distinguish interferences from prior invention generally, and provided that a person shall be entitled to a patent unless “before the applicant’s invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.” § 102(g) (1994) (emphasis added).

Applying the pre-AIPA version of § 102(g) in an interference case, this court stated in Scott v. Koyama, 281 F.3d 1243 (Fed. Cir. 2002), that “the inventor of an invention of foreign origin may rely on the date that the invention was disclosed in the United States[ ] as a conception date for priority purposes.” Id. at 1247 (citing Thomas v. Reese, 1880 Off. Gaz. Pat. Office 196, 198 (“If [an inventor], having conceived [the invention] and reduced it to practice in a foreign country *** communicates it to an agent in the United States for the purpose of obtaining letters patent or of introducing it to public use in the United States, he may, in an interference, carry the date of his invention back to the day in which it was fully disclosed to such agent in the United States.”)). Because nothing in the legislative history indicates that Congress attempted to abandon this court’s interpretation of the “made in this country” language of the pre-AIPA version of § 102(g) when it amended the statute and retained the language in § 102(g)(2), this court holds that the court’s interpretation of this language in Scott governs this noninterference, prior invention case under § 102(g)(2). See Lorillard v. Pons, 434 U.S. 575, 581 (1978) (“[W]here *** Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute.”). This court’s interpretation of the “made in this country” language of § 102(g) (1994) in Scott is consistent with how both parties in this appeal and district courts have interpreted the
“made in this country” language of § 102(g)(2) as it applies to prior invention, outside of the interference context. See Solvay S.A. v. Honeywell Specialty Materials LLC, 827 F. Supp. 2d 358, 363-64 (D. Del. 2011) (“[N]o authority indicat[es] that the language of § 102(g)(2) should be interpreted differently than that same language had been interpreted before the 1999 amendment.”), on remand from 622 F.3d 1367 (Fed. Cir. 2010); Theransense, Inc. v. Becton, Dickinson & Co., 560 F. Supp. 2d 835, 865 n.26 (N.D. Cal. 2008) (“[F]or an invention conceived outside the United States, the date of conception for purposes of priority for a United States patent is the date the invention is first reported to the inventor’s agent within the United States.” (citing Scott, 281 F.3d at 1247)).

2. Sufficiency of Disclosure

Amkor accepts Scott as binding—and thus does not contest that domestic disclosure and reduction to practice may be sufficient to satisfy the “made in this country” requirement of § 102(g)(2)—but argues that Scott requires a full disclosure of the invention in writing for a foreign invention to be deemed “made in this country” under § 102(g)(2). According to Amkor, “[t]he Commission’s new broad and lax standard” permitting “any U.S. disclosure—oral or otherwise—of a foreign conception to qualify as a U.S. conception date” “would lead to absurd results and would effectively eliminate the ‘made in this country’ requirements from § 102(g)(2).”

The Commission counters that Scott does “not in any way limit the disclosure of the invention to the written form.” According to the Commission, the word “communicate” in the domestic disclosure rule, by definition, includes oral and written conveyances. Carsem contends, relying on Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350 (Fed. Cir. 2001), that the only difference between written and oral disclosure is that “[w]hen an inventor, foreign or domestic, orally discloses an invention in the United States, independent corroboration is required.” Both the Commission and Carsem argue that to be “made in this country” under § 102(g)(2), a foreign invention need only be disclosed in the United States in a manner sufficient to show conception, i.e., “the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice,” Burroughs Wellcome Co. v. Barr Labs. Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) (citing Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)), which may occur orally or in writing.

The domestic disclosure rule cited in Scott, first articulated in Thomas, provides that an inventor who “communicates [his invention] to an agent in the United States *** may *** carry the date of his invention back to the day in which it was fully disclosed to such agent in the United States.” 281 F.3d at 1247 (citing Thomas, 1880 Off. Gaz. Pat. Office at 198). Under this rule, domestic disclosure is satisfied by a “communication” that “fully disclose[s]” the invention. Id. It is generally understood that a “communication” may occur orally or in writing. See, e.g., Oxford English Dictionary (3d ed. 2009) (defining “communicate” as “[t]o impart (information, knowledge, or the like) *** ; to convey, express”); Webster’s Third New In-
ternational Dictionary, Unabridged (2002) (defining “communicate” as to “speak, gesticulate, or write to another to convey information”).

While this court’s limited precedent on this issue establishes that writings can satisfy the full domestic disclosure requirement, the cases do not establish any per se requirement that such disclosure must be in writing. See Scott, 281 F.3d at 1246-47 (finding prior conception in the United States where both parties conceded that “a full description of the process of the count was contained in written materials disclosed to persons at ICI Americas,” but articulating the requirement only as “disclos[ure] in the United States”); Holmwood v. Sugavanam, 948 F.2d 1236, 1238-40 (Fed. Cir. 1991) (finding prior reduction to practice in the United States based on domestic testing of a foreign fungicide, proof of which was established through oral testimony and test results); Mortsell v. Laurila, 301 F.2d 947, 951 (CCPA 1962) (finding prior conception in the United States based solely on the oral testimony of the applicant’s United States patent attorney and his employee, where the oral testimony established that the patent attorney’s secretary made a complete English language translation of a German patent application fully disclosing the invention). These cases require a domestic disclosure sufficient to establish conception.

Amkor is incorrect that the failure to import a writing requirement leads to a “broad and lax standard” where effectively any domestic disclosure would establish domestic conception. The content of the domestic disclosure must be specific enough to encompass the “complete and operative” invention, see Hybritech, 802 F.2d at 1376 (Fed. Cir. 1986), and an inventor’s oral testimony to this extent is a question of proof, see Sandt, 264 F.3d at 1350-51, and Price, 988 F.2d at 1194.

Amkor argues that Carsem failed to submit sufficient evidence to corroborate the ASAT inventor’s testimony that he fully disclosed the invention to his colleague in the United States prior to the critical date. However, even if the ASAT inventor’s domestic disclosure was sufficient—and this court is not persuaded that it was—the Commission erred in its priority date determination with respect to Amkor for the reasons explained below.

3. The Commission’s Application of Oka was Legal Error

In Oka, the junior party in an interference submitted a range of dates of possible conception in an attempt to prove prior invention under § 102(g). Oka, 849 F.2d at 584. This court held:

Because Oka is the senior party, Youssefyeh was required to establish reduction to practice before Oka’s filing date, or conception before that date coupled with reasonable diligence from just before that date to Youssefyeh’s filing date. The Board’s finding that Youssefyeh initiated preparation of a 5-inadanylnyl compound “in the last week of October 1980” supports the conclusion that Youssefyeh failed to establish conception, much less a reduction to practice, of that class of compounds earlier than October 31, 1980. In dealing with a reduction to practice, the court in Haultain v. DeWindt, 254 F.2d 141[, 142] (CCPA 1958), stated [that] *** “where testimony merely places the acts within a stated time period, the inventor has not established a date for his activities earlier than the last day of the period.” That rule is equally appropriate in establishing a date of
conception, nor does Youssefyeh dispute Oka’s position that “the last week in October” means October 31.

Thus Youssefyeh’s conception and Oka’s filing date are the same, i.e., October 31, 1980. Oka, as the senior party, is presumptively entitled to an award of priority, and Youssefyeh, as the junior party in an interference between pending applications, must overcome that presumption with a preponderance of the evidence. In the event of a tie, therefore, priority must be awarded to the senior party. Because Youssefyeh, the junior party, failed to show a conception date earlier than Oka’s filing date, Oka is entitled to priority. We reverse the Board’s award of priority to Youssefyeh.

849 F.2d at 584-85.

Amkor argues that the Oka rule—i.e., according the last possible conception date to a party who can only provide a range of dates—applies only to the party with the burden of persuasion on the issue of prior invention. Amkor further contends that because Carsem bore the burden of persuasion, the Oka rule applies only to the ASAT invention, not Amkor’s invention. Amkor argues under Oka that the ASAT invention is entitled to the last possible conception date in its April/May range, or May 31, which is later than Amkor’s May 1 through August 31 range of conception dates, “or at most a tie.”

Carsem counters that “the Oka rule applies to any party with a burden to prove a date of invention, whether that party is junior or senior [or] has the ultimate burden of persuasion.” Similarly, the Commission argues that “it [] would make no sense to have two different rules for determining the date of conception *** one applicable to a party that has the burden of persuasion, and another applicable to a party without such a burden.”

The Oka rule does not apply to patent owners like ASAT in validity disputes. This is not an interference, and the standards that apply to interferences do not necessarily apply to disputes over validity. An issued patent is entitled to a presumption of validity under 35 U.S.C. § 282, which can be overcome only with clear and convincing evidence. Microsoft Corp. v. i4i Ltd., 131 S.Ct. 2238, 2241 (2011); Sandt, 264 F.3d at 1350. The presumption of validity and the clear and convincing burden associated with it did not apply in the interference in Oka. In Oka, the question of entitlement to priority did not carry any presumption and was determined based on preponderant evidence. See Oka, 849 F.2d at 584. In Oka, even under the preponderant evidence standard, the junior party could not prove prior invention by presenting a range of dates that primarily predated but overlapped by one day with the senior party’s conception date. Id. at 584-85.

To invalidate Amkor’s ’277 Patent under § 102(g)(2), Carsem bore the burden of persuasion and was required to submit not just preponderant evidence but clear and convincing evidence that the ASAT invention was conceived in the United States before the invention of the ’277 Patent. Carsem could only show a range of dates of possible United States disclosure, the first 30 days of which pre-dated Amkor’s possible conception date, and the last 31 days of which overlapped with Amkor’s possible conception dates. Such a showing, at best, establishes that the ASAT inventor might have conceived of the invention first. Evidence establishing that there
might have been a prior conception is not sufficient to meet the clear and convincing burden needed to invalidate a patent. Accordingly, the ALJ was correct ... when he concluded that “Carsem [] failed to prove by clear and convincing evidence that the April/May [] date of invention *** is prior to the [May through August] date of invention accorded the asserted claims of the patents-in-suit.” The Commission committed legal error in reversing this determination based on an erroneous application of the Oka rule to the patent holder. Because Carsem failed to prove prior invention in the United States by clear and convincing evidence, this court reverses the Commission’s determination that the ’277 Patent is invalid under § 102(g)(2).

... For the foregoing reasons, this court reverses ... and remands for further proceedings consistent with this opinion.
Chapter 6: Nonobviousness

**Mueller’s Patent Law: 271-312**

**Electromechanical Cases**

**Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.**

485 F.3d 1157 (Fed. Cir. 2007)

**Lourie, Judge:**

Leapfrog Enterprises, Inc. appeals from the order ... entering judgment of non-infringement and invalidity of claim 25 of Leapfrog’s U.S. Patent 5,813,861 in favor of Fisher-Price, Inc. and Mattel, Inc. (collectively “Fisher-Price”). We affirm.

**Background**

Leapfrog filed suit in October 2003, alleging that Fisher-Price’s PowerTouch product infringed claim 25 of the ’861 patent. ... The ’861 patent relates to a learning device to help young children read phonetically. Claim 25 reads as follows:

An interactive learning device, comprising:
- a housing including a plurality of switches;
- a sound production device in communication with the switches and including a processor and a memory;
- at least one depiction of a sequence of letters, each letter being associable with a switch; and
- a reader configured to communicate the identity of the depiction to the processor,

wherein selection of a depicted letter activates an associated switch to communicate with the processor, causing the sound production device to generate a signal corresponding to a sound associated with the selected letter, the sound being determined by a position of the letter in the sequence of letters.

’861 patent, col. 10, ll. 23-36.

... The trial court issued its decision on March 30, 2006, finding claim 25 of the ’861 ... invalid as obvious. The court ... concluded that claim 25 was invalid as obvious in view of the combination of U.S. Patent No. 3,748, 748 to Bevan, the Texas Instruments Super Speak & Read (“SSR”) device, and the knowledge of one of ordinary skill in the art as represented by the
testimony of Fisher-Price’s technical expert, Ronald Milner.

Discussion

“Obviousness is a question of law, reviewed de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial.” Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1289 (Fed. Cir. 2006).

Leapfrog argues that the district court engaged in improper hindsight in reaching its conclusion of obviousness by concluding that all of the limitations of the claim are found in the prior art. Leapfrog also argues that the court’s finding that the Bevan device has the same functionality as claim 25 was clearly erroneous because the components of Bevan’s device are mechanical, and thus different in structure and interrelation from the electronic components described in claim 25, and therefore cannot provide the same functionality. Leapfrog argues that there was inadequate evidence in the record to support a motivation to combine Bevan, the Texas Instruments SSR, and a reader to arrive at the invention of claim 25. Finally, Leapfrog argues that the district court did not properly consider the strong evidence of secondary considerations of nonobviousness.

In response, Fisher-Price argues that claim 25 is nothing more than the Bevan device, a toy that teaches reading based on the association of letters with their phonemic sounds, updated with modern electronics that were common by the time of the alleged invention. Fisher-Price also responds that particularized and specific motivations to combine need not be found in the prior art references themselves in the context of an improvement that arises from a desire to generally improve a known device (e.g., to make the product smaller, lighter, or less expensive) using newer technology. Finally, Fisher-Price argues that the district court did give proper consideration to secondary considerations of nonobviousness, but simply concluded that those considerations were not sufficient to overcome the determination of obviousness based on primary considerations.

We agree with Fisher-Price that the district court correctly concluded that the subject matter of claim 25 of the ’861 patent would have been obvious in view of the combination of Bevan, the SSR, and the knowledge of one of ordinary skill in the art. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). Thus, we bear in mind that the goal of the claim 25 device was to allow a child to press a switch associated with a single letter in a word and hear the sound of the letter as it is used in that word. In this way, the child would both associate the sound of the letter with the letter itself and be able to sound out the word one letter at a time to learn to read phonetically. Accommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to
one of ordinary skill in designing children’s learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years.

The Bevan patent was one of the pieces of prior art relied upon by the district court, and it describes an electro-mechanical learning toy. In the preferred embodiment of the Bevan device, a housing contains a phonograph record as a voice storage means, a speaker for playing sounds from the voice storage means, and an actuated electric motor to turn the record. Uniquely shaped puzzle pieces fit into correspondingly shaped openings in the top of the housing. Depressing the puzzle pieces in the openings causes the motor to turn the record and brings phonographic needles into contact with the portions of the record where the sounds associated with the puzzle pieces are stored so that they can be played through the speaker. In one embodiment, each puzzle piece is imprinted with one letter from a word, and pressing each puzzle piece produces the sound of a single letter in that word. Thus, although it relies on an electric motor and mechanical structures rather than a processor and related electronics, Bevan teaches an apparatus that achieves the goals described above of associating letters with their sounds and encouraging children to sound out words phonetically through a similar type of interaction. We therefore see no clear error in the district court’s finding that the Bevan device has the same method of operation, viewed as a whole, as claim 25 of Leapfrog’s ’861 patent.

A second piece of prior art relied upon by the district court was the Texas Instruments SSR. The SSR is a more modern type of prior art learning toy, constructed with electronic components, that has a slightly different mode of operation than Bevan. The SSR has a hinged plastic housing that opens to lie flat. Books for use with the toy fit into a recess in the housing. The housing contains switches that can detect when a child presses on different areas of the books’ pages. The housing also contains a processor, memory, and a speaker to produce sounds. In one mode of operation, the SSR allows the child to press the first letter of a word and hear the sound of that letter. The remainder of the letters in the word are grouped together and played together. For example, the child can press the letter “t” and hear the t phoneme and then press “ug” to hear all the sounds in the word “tug.” Similarly, the child can press the letter “b” and then “ug” to hear the sounds in “bug.” The SSR does not include a reader that allows the processor to automatically identify the inserted book. Instead, the user can press a triangle printed on the first page of the book, and the processor determines from the location of the triangle printed on the
Similarly, the user can press a star on each page of the book, and the processor determines from the location of the star on the page which page of the book is being viewed. Thus, the SSR provides a roadmap for one of ordinary skill in the art designing to produce an electronics-based learning toy for children that allows the use of phonetic-based learning methods, including the association of individual letters with their phonemes.

We agree with the district court that one of ordinary skill in the art of children’s learning toys would have found it obvious to combine the Bevan device with the SSR to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation, and reduced cost. While the SSR only permits generation of a sound corresponding to the first letter of a word, it does so using electronic means. The combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR). We therefore also find no clear error in the finding of the district court that one of ordinary skill in the art could have utilized the electronics of the SSR device, with the method of operation taught by Bevan, to allow a child to press each individual letter in a word and hear the individual phonemes associated with each letter to sound out the words.

This combination of Bevan and the SSR lacks only the “reader” of claim 25 of the ’861 patent. The district court found that readers were well-known in the art at the time of the invention. As there is ample evidence in the record to support that finding, we find no clear error in the court’s determination. Furthermore, the reasons for adding a reader to the Bevan/SSR combination are the same as those for using readers in other children’s toys—namely, providing an added benefit and simplified use of the toy for the child in order to increase its marketability. Leapfrog presents no evidence that the inclusion of a reader in this type of device was uniquely challenging or difficult for one of ordinary skill in the art. See KSR, 550 U.S. at 418. Nor does Leapfrog present any evidence that the inclusion of a device commonly used in the field of electronics (a reader), and even in the narrower art of electronic children’s toys, represented an unobvious step over the prior art. Our conclusion is further reinforced by testimony from the sole inventor at trial that he did not have a technical background, could not have actually built the prototype himself, and relied on the assistance of an electrical engineer and Sandia National Laboratory to build a prototype of his invention.

Finally, we do not agree with Leapfrog that the court failed to give proper consideration to secondary considerations. The district court explicitly stated in its opinion that Leapfrog had provided substantial evidence of commercial success, praise,
and long-felt need, but that, given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that claim 25 would have been obvious. We have no basis to disagree with the district court’s conclusion.

In light of our review of the evidence and the lack of any clear error in the district court’s factual findings, we agree with the district court’s conclusion that claim 25 of the ’861 is invalid as obvious in view of the combination of Bevan, the SSR device, and the knowledge of one of ordinary skill in the art concerning readers.

…

Agrizap, Inc. v. Woodstream Corp.
520 F.3d 1337 (Fed. Cir. 2008)

Moore, Judge:

Agrizap, Inc. has sued Woodstream Corporation … for fraudulent misrepresentation and infringement of U.S. Patent No. 5,949,636, which pertains to an electronic rodent-killing device. Woodstream appeals the district court’s denial of its motion for judgment as a matter of law … for invalidity and unenforceability. Agrizap cross-appeals the district court’s final judgment of noninfringement.

… Though we defer to the jury for its fact findings on obviousness, we ultimately conclude that, despite those findings, the patent claims in dispute are invalid for obviousness and thus reverse the district court’s denial of Woodstream’s JMOL in that respect. As our decision on those issues completely resolves this case, we decline to address the other arguments ….

Background

Agrizap is the holder of the ’636 patent, which relates to a method and apparatus for electrocuting pests, such as gophers, rats, and the like. The disclosed invention operates by sensing the presence of a pest with a resistive switch. When the hapless pest makes contact with a high voltage electrode and a reference electrode, its body creates a leakage current that completes an electric circuit and triggers a generator. The generator then produces a voltage and current of sufficiently high magnitude to send the pest towards its demise. After the expiration of a predetermined amount of time, the generator deactivates and cannot be retriggered to dispatch another pest until the invention is reset by turning it off and then on again.

In March of 2000, Woodstream, a nationwide distributor of pest control products such as traditional snap traps and glue traps, approached Agrizap about marketing the Rat Zapper, the commercial embodiment of the ’636 patent. The two parties engaged in negotiations from April 2000 to September 2000. During this time, they signed a mutual confidentiality agreement that permitted either party to disclose certain secret and proprietary information for the purposes of assessing Woodstream’s interest in purchasing Agrizap’s products and forming a business relationship with Agrizap.

In July 2000, without Agrizap’s knowledge, Woodstream sent samples of the Rat Zapper to offshore Chinese manufacturers. Upon learning of Woodstream’s actions, in August 2000, Agrizap’s president, Robert Noe, emailed Woodstream’s ex-
ecutive vice president, Andy Woolworth, seeking written assurance that Woodstream’s actions fell within the terms of their confidentiality agreement. Woolworth responded but did not directly address the confidentiality agreement. This prompted Noe to send a second email repeating his original request for assurances. Only then did Woolworth respond, “Bob – Please reference our point 5 of the confidentiality agreement to cover your concern below. We asked a source *** to quote on the product.”

Roughly five days later, unbeknownst to Agrizap, Woodstream instructed its Chinese supplier that it would make the product itself. At trial, Woodstream admitted that its vice president had not actually read the confidentiality agreement. An internal Woodstream document produced at that time revealed: “We are going through Agrizap in the short term to give Woodstream access to the technology.”

At the end of negotiations, the parties established an oral marketing agreement whereby Agrizap would fulfill Woodstream’s purchase orders at a lower wholesale price. The products would still be named “Rat Zapper,” but would use Woodstream’s Victor brand label. Woodstream agreed to distribute the Rat Zappers to large retail stores, such as Home Depot, Ace, and Lowe’s. Agrizap agreed not to compete with Woodstream in these venues. Accordingly, from 2000-2003, Agrizap delivered 11,100 units of the Rat Zappers with the Victor label to Woodstream for a total of $226,000.

In 2003, Woodstream released its Electronic Mouse Trap (EMT) and in 2004, its Electronic Rat Trap (ERT). Upon learning of the ERT in 2004, Agrizap terminated its relationship with Woodstream. …

Agrizap sued Woodstream, alleging that Woodstream fraudulently misrepresented its motive behind sending the Rat Zappers overseas. … Agrizap also sued Woodstream for infringement of independent claim 1 and dependent claims 2, 3, 5, and 10, and independent claim 16 of the ‘636 patent. Woodstream presented a vast arsenal of affirmative defenses … .

The jury returned a verdict in favor of Agrizap on the fraudulent misrepresentation claim and awarded $1,275,000 in past and future damages. As for Agrizap’s patent infringement claims, the jury found none of Woodstream’s affirmative defenses viable. Determining that Woodstream had infringed independent claim 16, but not independent claim 1 or its dependent claims, the jury awarded $1,425,000 in damages.

…

Discussion

…

Because the patent law aspects of this case can be decided entirely on the grounds of obviousness—notwithstanding the panoply of issues raised by the parties on appeal—we limit our discussion to only that which is necessary.

We review the underpinning facts of a jury verdict of nonobviousness for substantial evidence, according due deference to the jury, as always, in its role as the factfinder. See Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 719 (Fed. Cir. 1984). Our review of the facts, regardless of whether they are explicit or
implicit within the verdict, is bound by this high level of deference. See LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001). Thus, even when the jury is given an essentially black box verdict form—that is, a form that merely asks the jury to answer “yes” or “no” as to whether a claim is obvious, such as was done in this case—we presume all factual disputes were resolved in favor of the verdict. See Jurgens v. McKasy, 927 F.2d 1552, 1557 (Fed. Cir. 1991).

However, as the ultimate conclusion of obviousness is a question of law, it remains our duty as the appellate court to ensure that the law has been correctly applied to the facts. Structural Rubber Prods., 749 F.2d at 719. In other words, we review de novo the conclusion on obviousness. Though we are fully cognizant of the hindsight bias that often plagues determinations of obviousness, Graham v. John Deere Co., 383 U.S. 1, 36 (1966), we are also mindful that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results,” KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007).

During prosecution, the PTO rejected Agrizap’s application for the ’636 patent as being unpatentable over the claims of U.S. Patent No. 5,269,091 in view of U.S. Patent No. 4,048,746 (the Dye patent) and U.S. Patent No. 4,200,809 (the Madsen patent), due to obviousness-type double patenting.[†] The ’091 patent, a patent that Agrizap obtained before the ’636 patent, is also directed to a pest electrocution device and discloses all of the limitations of the asserted claims in the ’636 patent with one exception—it discloses a mechanical switch instead of a resistive switch to complete its circuit. At two separate trade shows in California in February of 1993, Agrizap demonstrated a commercial embodiment of the ’091 patent, the Gopher Zapper. It is undisputed that, while the PTO was aware of the ’091 patent, it was not aware of the public use of its commercial embodiment.

The Dye patent, which Agrizap’s expert described as a “killer cane,” discloses “[a]n electronic executing device used to demise gophers and other underground rodents” wherein the presence of the rodent completes the circuit when it touches two separate contact points. While the Madsen patent does not pertain to pest control, it discloses an apparatus akin to a

† [ Ed. Note—As Mueller’s Patent Law explains, at 701, “double patenting” is the “prohibition against the issuance of more than one U.S. patent on a particular invention. If an applicant attempts to obtain a second patent claiming the same invention or an obvious variant of the invention he has previously patented, he may confront a USPTO rejection of the second application’s claims on the basis of double patenting. … [O]bviousness-type double patenting rejections may be overcome by the filing of a terminal disclaimer in accordance with 35 U.S.C. § 253, ¶ 2.”]
cattle prod that generates an electric charge when an external load, such as the body of a cow, completes a circuit by crossing two electrodes and creating a resistance current. Notably, in its rejection, the PTO explained that “[t]he patented claims differ [from the claims of the ’091 patent] in the type of sensor used to effect the electrocution. ... Thus the obvious substitution is that of the above combination of DYE and MADSEN as set forth above in detail regarding the use of electrocution via the resistive sensing electrodes.” In response, Agrizap corrected the inventorship for the ’636 patent so that both the ’636 patent and the ’091 patent had the same inventor and filed for terminal disclaimer. This eliminated the ’091 patent as a basis for rejection [on an] obviousness-type double patenting [theory].

Woodstream contends on appeal that the claims of the ’636 patent are obvious and thus invalid in light of the Gopher Zapper, the Dye patent, and the Madsen patent. In support, Woodstream argues that the examiner properly rejected the asserted claims during prosecution based on the ’091 patent, the Dye patent, and the Madsen patent—a combination of prior art identical to that which has been presented by Woodstream on appeal. While Agrizap’s correction of inventorship disqualified the ’091 patent as a basis for a double patenting rejection, it did not disqualify the commercial embodiment of that patent, the Gopher Zapper, from being considered as prior art. The parties do not dispute that the Gopher Zapper was used in public more than a year before the filing date of the ’636 patent and is therefore prior art. Moreover, there is no dispute that the ’091 patent and, in turn, the Gopher Zapper disclose every single limitation of the asserted claims save for the resistive switch that is disclosed in the Madsen and Dye patents. See Oral Arg. 33:56-36:42 (Feb. 7, 2008). Thus, we effectively find ourselves in the curious position of reviewing the same prior art that the PTO relied upon to reject the asserted claims.

Certainly, the PTO’s rejection in light of this identical prior art is by no means dispositive of the issues that need to be resolved to determine the validity of the asserted claims. The PTO was never presented with the objective evidence of nonobviousness, including the commercial success of the Rat Zapper, copying by Woodstream, and a long felt need in the market for electronic rat traps, which was presented to the jury. Even when we presume the jury found that the objective evidence of nonobviousness favored Agrizap, this evidence is insufficient to overcome the overwhelming strength of Woodstream’s prima facie case of obviousness.

This is a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results. KSR, 550 U.S. at 416. The only difference between the Gopher Zapper and the asserted claims, as conceded by Agrizap, is the type of switch used to complete the circuit that triggers the generator. The asserted claims simply substitute a resistive electrical switch for the mechanical pressure switch employed by the Gopher Zapper. As illustrated by the Dye and Madsen patents, the use of an animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art. In favoring resistive switches over mechanical switches, both the Dye and Madsen patents are directed to solving the same problem as the ’636 patent—the malfunction of mechanical switches in en-
environments prone to dirt and dampness. See ’746 patent, col. 1, ll. 43-46, 53-63; ’809 patent, col. 1, ll.31-55.

In this case, the objective evidence of nonobviousness simply cannot overcome such a strong prima facie case of obviousness. Similarly, in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, we held that the objective considerations of nonobviousness presented in that case, including substantial evidence of commercial success, praise, and long-felt need, were inadequate to overcome a strong showing of primary considerations that rendered the claims at issue invalid. 485 F.3d 1157, 1162 (Fed. Cir. 2007). Based on the foregoing, we reverse the district court’s denial of Woodstream’s motion for JMOL as to the obviousness of the asserted claims.

... 

**In re Giannelli**

739 F.3d 1375 (Fed. Cir. 2014)

*Lourie, Judge:*

Raymond Giannelli appeals from the decision of the [PTO Board] affirming the rejection of claims 1-25 of U.S. Patent Application 10/378,261 under 35 U.S.C. § 103(a) as obvious over U.S. Patent 5,997,447. Because the Board erred in concluding that the claims of the ’261 application would have been obvious in view of the ’447 patent, we reverse.

**Background**

Giannelli filed the ’261 application, entitled “Rowing Machine,” in March 2003. The ’261 application discloses an exercise machine on which a user can perform a rowing motion against a selected resistance, thereby strengthening the back muscles. ’261 application, at 2-3.

Claim 1, as amended, is representative of the claims on appeal and reads as follows:

1. A row exercise machine comprising an input assembly including a first handle portion adapted to be moved from a first position to a second position by a pulling force exerted by a user on the first handle portion in a rowing motion, the input assembly defining a substantially linear path for the first handle portion from the first position to the second position.


The specification teaches that the rowing machine’s arms travel in a substantially linear path as the handles are pulled. ’261 application, at 3-4. An exemplary method of operation described in the specification depicts the user as pulling the machine’s handles to overcome a selected resistance. Figure 4 of the ’261 application ... shows a left side view of an embodiment of the row exercise machine.
The PTO examiner initially rejected all the original claims of the ’261 application, finding the claims anticipated by the ’447 patent.

The ’447 patent, entitled “Chest Press Apparatus for Exercising Regions of the Upper Body,” describes a chest press exercise machine where the user performs the exercise by pushing on the handles to overcome the selected resistance. ’447 patent, col. 11, ll. 39-50. Figure 1 of the ’447 patent ... depicts an angled view of the chest press apparatus.

In response to the rejection, Giannelli amended the claims to add the limitation “by a pulling force exerted by a user on the first handle portion in a rowing motion,” but the examiner again rejected the ’261 application under 35 U.S.C. §§ 102(b) and 103(a) in view of the ’447 patent. The rejection was made final.

Giannelli appealed the examiner’s rejection to the Board. The Board affirmed the obviousness rejection and did not address the anticipation rejection. The Board characterized the dispositive issue as being whether the chest press machine of the ’447 patent was “capable of being used by exerting a pulling force on the handles in a rowing motion.” The Board deemed it reasonable that a user could face the handles of the prior art chest press machine and exert a pulling force on its handles in a rowing motion. The Board noted that the recitation of a new intended use for an old product did not make a claim to that old product patentable, and consequently determined that the ’261 application simply recited the new intended use of rowing for the ’447 patent chest press apparatus. The Board further found that even though using the ’447 patent’s invention as a rowing machine “may not fully achieve the ‘purpose’ of [the ’447] apparatus,” Giannelli had not shown that the apparatus could not be used in such a manner. In the Board’s view, Giannelli thus failed to rebut the Board’s showing of capability of pulling the handles. The Board also found that the ’261 application’s claimed “substantially linear path” encompassed the “slightly curvilinear path” disclosed in the ’447 patent Abstract.

Discussion

We review the Board’s legal conclusions de novo, In re Elsner, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and the Board’s factual findings underlying those determinations for substantial evidence, In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding. Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Obviousness is a question of law, based on underlying factual findings. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); Elsner, 381 F.3d at 1127. ...
Giannelli argues that the Board’s decision sustaining the examiner’s rejection is based on an incorrect assertion that the chest press machine disclosed in the ’447 patent could be used as a rowing machine rather than considering how it would be used. Giannelli contends that the Board erred in concluding that the examiner had met the burden of establishing a case of prima facie obviousness over the cited ’447 reference because he failed to explain how or why a user could possibly use the prior art chest press machine to perform a rowing motion. The Director responds that claim 1 only requires an exercise machine with handles that can be pulled. The Director contends that the Board correctly found that the chest press machine described in the ’447 patent either disclosed or rendered obvious all of the limitations of the ’261 application claims. The Director further contends that the Board correctly held that Giannelli did not rebut the finding of capability because he did not provide any persuasive argument or evidence to show that the chest press machine described in the ’447 patent could not be used to perform the rowing exercise.

The Board did not review and decide the anticipation issue, so neither will we. Thus, it is obviousness that is before us, and we conclude that the Board erred in concluding that the claims of the ’261 application would have been obvious in view of the ’447 patent. The Board premised its conclusion on its theory that the machine described in the ’447 patent was “capable of” having its handles pulled.

The PTO bears the initial burden of showing a prima facie case of obviousness. In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007). When a prima facie case of obviousness is made, the burden then shifts to the applicant to come forward with evidence and/or argument supporting patentability. In re Glaug, 283 F.3d 1335, 1338 (Fed. Cir. 2002). The PTO did not carry its burden in this case.

The claims of the ’261 application specifically require a “first handle portion adapted to be moved from a first position to a second position by a pulling force … in a rowing motion.” We have noted that, “the phrase ‘adapted to’ is frequently used to mean ‘made to,’ ‘designed to,’ or ‘configured to,’ … .” Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672 F.3d 1335, 1349 (Fed. Cir. 2012). Although the phrase can also mean “‘capable of’ or ‘suitable for,’” id., here the written description makes clear that “adapted to,” as used in the ’261 application, has a narrower meaning, viz., that the claimed machine is designed or constructed to be used as a rowing machine whereby a pulling force is exerted on the handles.

The written description of the ’261 application describes how the position of the handles relative to the primary and secondary lever arms and the resistance mechanism renders them “adapted” to be moved by the user’s pulling force. For example, the application states that the exercise machine “enables a user to maintain biomechanical alignment of the user’s wrist and forearm during performance of the exercise, while maintaining a consistent resistance applied to the muscles, in the stability of an exercise machine.” ’261 application, at 3. The location of those handles relative to the other components is one of their structural attributes that enables performance of the rowing motion against the selected resistance. ’261 application, at 4 (“The declining, substantially linear path [of the pulled handles] enables the user to maintain proper biomechanical alignment of the force angle being applied to the grip. This allows for a fairly consistent torque application at the shoulder...
throughout the range of motion of the exercise.”). Consequently, the relevant question before the Board was whether the apparatus described in the ’447 patent was “‘made to,’ ‘designed to,’ or ‘configured to,’” allow the user to perform a rowing exercise by pulling on the handles as claimed in the ’261 application.

There is no question that the ’447 patent does not have handles that are adapted to be pulled in a rowing motion. The ’447 patent’s written description describes the exercise machine’s structure as allowing a movement that “simulates as natural a human musculoskeletal outward pushing motion as possible while maintaining proper biomechanical alignment of the user’s joints.” ’447 patent col. 11, ll. 61-64; see also id. col. 2, ll. 37-41 (stating that the position of the machine and handles allows the exercising user to “maintain the proper biomechanical alignment of the joints” and the proper alignment of the wrists”). The Board stated that using the ’447 patent as a rowing machine was a new intended use of the prior art apparatus. In the context of the claimed rowing machine, however, the mere capability of pulling the handles is not the inquiry that the Board should have made; it should have determined whether it would have been obvious to modify the prior art apparatus to arrive at the claimed rowing machine. Because the Board determined that the machine claimed in the ’261 application would have been obvious by merely showing that a rowing exercise could be performed on the machine disclosed in the ’447 patent, and not whether it was obvious to modify the chest press machine to contain handles “adapted to” perform the rowing motion by pulling on them, the Board erred in concluding that the examiner had met his initial burden of establishing a case of prima facie obviousness. Sullivan, 498 F.3d at 1351.

Physical capability alone does not render obvious that which is contraindicated. And, on this record, it is not obvious to modify a machine with handles designed to be pushed to one with handles adapted to be pulled. A chest press machine is not a rowing machine, nor has evidence been shown that it is. In fact, anyone who has used exercise machines knows that a sure-fire way to cause injury is to use a machine in a manner not intended by the manufacturer.

Because the Board’s analysis began with the premise that “adapted to” meant “capable of,” its affirmance of the examiner’s rejection also contained no explanation why or how a person having ordinary skill in the art would modify the prior art chest press machine to arrive at the apparatus of the ’261 application. And because the initial burden was not met, Giannelli was not obligated to submit additional evidence to rebut the examiner’s findings of pulling capability. See In re Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (“Only if that burden [of establishing a prima facie case] is met, does the burden of coming forward with evidence or argument shift to the applicant.”). The Board thus erred in affirming the conclusion of the examiner that the ’447 patent apparatus rendered obvious the claimed invention of the ’261 application.

As indicated earlier, the Board did not review the examiner’s anticipation rejection, so neither will we. However, as we are reversing the Board’s obviousness conclusion, it is hard to see how these claims could have been anticipated by the cited ’447 patent.
Finally, we do not need to address the distinction between the “substantially linear” path claimed in the ’261 application and the “slightly curvilinear” path disclosed in the ’447 patent. At oral argument, counsel for Giannelli conceded that the two phrases are not inconsistent. Oral Argument at 2:50, In re Giannelli, Case No. 2013-1167, available at http://www.cafc.uscourts.gov/oralargumentrecordings/13-1167/all.

... 

The “Analogous Arts” Question

Innovention Toys, LLC v. MGA Entertainment, Inc.

637 F.3d 1314 (Fed. Cir. 2011)

Lourie, Judge:

MGA Entertainment, Inc. [and others] (collectively, “MGA”) appeal from the summary judgment decision … that the asserted claims of U.S. Patent 7,264,242 were infringed and were not invalid for obviousness. … The district court … erred in several of its factual findings underlying its nonobviousness determination. We therefore vacate the court’s grant of summary judgment of nonobviousness and remand.

Background

I.

Innovention Toys, LLC (“Innovention”) brought suit against MGA for infringement of the ’242 patent, which claims a chess-like, light-reflecting board game and methods of playing the same. The disclosed game includes a chess-styled playing surface, laser sources positioned to project light beams over the playing surface when “fired,” mirrored and non-mirrored playing pieces used to direct the lasers’ beams, and non-mirrored “key playing pieces” equivalent to the king pieces in chess. To play the game, players take turns either moving a playing piece to an unoccupied, adjacent square or rotating (reorienting) a piece within a square. After moving or rotating a piece, a player then fires his laser, and if the laser’s beam strikes the non-mirrored surface of a playing piece, that piece is eliminated from the game. To win the game, a player must direct his laser beam to strike, or illuminate, his opponent’s non-mirrored key playing piece, ending the game.

All the asserted claims … include a “key playing pieces” limitation in which the key pieces are “movable.” Claim 31 is representative:

A board game for two opposing players or teams of players comprising:

a game board, movable playing pieces having at least one mirrored surface, movable key playing pieces having no mirrored surfaces, and a laser source,

wherein alternate turns are taken to move playing pieces for the purpose of deflecting laser beams, so as to illuminate the key playing piece of the opponent.

(Emphasis added.)
MGA counterclaimed, denying infringement and alleging, inter alia, that the ’242 patent was invalid under 35 U.S.C. § 103. In making its obviousness argument, MGA relied on the combination of (1) two articles describing computer-based, chess-like strategy games, Laser Chess and Advanced Laser Chess (collectively, “the Laser Chess references”); and (2) U.S. Patent 5,145,182 (“the Swift patent”) describing a physical, chess-like, laser-based strategy game.

The Laser Chess game is described in an article entitled “Laser Chess First Prize $5,000.00 Winner Atari ST Programming Contest,” published in the April 1987 edition of Compute!. Advanced Laser Chess is described in an article published in the Summer 1989 edition of Compute!’s Amiga Resource. Both articles disclose chess-like computer games with virtual lasers and mirrored and non-mirrored pieces, which are moved or rotated by players during alternating turns on a virtual, chess-like playing board. The goal of each game is to manipulate one’s laser beam using the various game pieces to eliminate the other player’s non-mirrored king piece by striking it with the laser beam. In Laser Chess, a player’s king piece may move squares during game play: “[The king] can capture any opposing piece by moving onto its square.” Similarly, in Advanced Laser Chess “Kings possess the ability to capture other pieces [by moving on top of them].”

The Swift patent discloses a physical (rather than electronic) strategy game in which players take turns placing mirrored game pieces onto squares of a chess-styled game board. The players position the pieces so as to direct their laser’s beam towards the opposing player’s scoring module and away from their own. A player scores when his laser beam, having been deflected around the game board, strikes his opponent’s scoring module. The scoring modules are mounted to the frame of the game board and thus are not physically capable of movement on the game board.

MGA’s accused game, Laser Battle, is a physical board game for playing a chess-like strategy game. Players take turns moving or rotating mirrored playing pieces so as to direct a laser beam to strike the opposing player’s non-mirrored Tower playing piece to win the game.

II.

On October 14, 2009, the district court ruled on the parties’ cross-motions for summary judgment of infringement and invalidity. The district court granted Innovention’s motion for summary judgment of literal infringement.

The district court also granted Innovention’s motion for summary judgment of nonobviousness. The court first found that the Laser Chess references were non-analogous art because they described electronic, rather than real-world, laser games. The district court then held that, because MGA had provided no evidence to support a finding as to the level of ordinary skill in the art, MGA’s obviousness argument could be pursued only on the basis of what would have been obvious to a layperson. The court then decided that because MGA had not provided any evidence that a layperson would have known of the Laser Chess articles or would have had
any reason to modify the teachings of the Laser Chess references, MGA had failed to state a *prima facie* case of obviousness.

Finally, the court found that Innovention had demonstrated several secondary considerations of nonobviousness. These included (1) commercial success based on the sale of 140,000 games by Innovention, a small company with minimal marketing capabilities, and evidence that fans had started clubs and tournaments around the world; (2) long-felt need based on the game’s sudden success and media praise; and (3) industry praise based on, inter alia, the game’s nomination for Outstanding Technology of the Year by the International Academy of Science and its being one of five finalists for the Toy Industry Association’s 2007 Game of the Year award. In light of its summary judgment rulings, the district court granted Innovention’s motion for a permanent injunction on January 13, 2010.

MGA appealed. …

Discussion

…

II. Obviousness

… Although the ultimate determination of obviousness under § 103 is a question of law, it is based on several underlying factual findings, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). …

MGA argues that, rather than being nonobvious, the asserted claims would have been obvious based on the combination of the Laser Chess references, which teach the claimed game in electronic form, and the Swift patent, which teaches a physical laser-based game. According to MGA, the district court erred both (1) in concluding that because the ’242 patent relates to a physical game, the Laser Chess articles were non-analogous art; and (2) in assuming that a person of skill in the art was a layperson rather than, as put forth by Innovention, a mechanical engineer with knowledge of optics. Finally, MGA argues, Innovention’s unsupported and conclusory assertions of secondary considerations fail to overcome MGA’s *prima facie* case of obviousness.

Innovention responds that the Laser Chess references in combination with the Swift patent fail to teach or suggest every limitation of the asserted claims, and thus MGA has failed to state a *prima facie* case of obviousness. Specifically, Innovention argues that Swift, as MGA admits, fails to disclose movable key pieces and that the Laser Chess references fail to disclose any physical, non-virtual game components. Accordingly, Innovention argues that the Laser Chess references are non-analogous art because they are neither within the inventors’ field of endeavor, *i.e.*, a non-virtual, three-dimensional, laser board game, nor reasonably pertinent to it. Innovention also argues that because MGA offered no evidence as to the level of skill in the art, the skill level defaults to that of a layperson, and that its evidence of secondary considerations provides further evidence that the claimed invention would not have been obvious.
We conclude that the district court clearly erred in several of the factual findings underlying its obviousness analysis. The district court erred in finding that the Laser Chess references fail to qualify as analogous art. The court also erred in concluding that the level of skill in the art is that of a layperson. We address each in turn.

A. Analogous Art

A reference qualifies as prior art for a determination under § 103 when it is analogous to the claimed invention. *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992). “Two separate tests define the scope of analogous art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). “A reference is reasonably pertinent if *** it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *Clay*, 966 F.2d at 659. “If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection.” *Id*. Whether a prior art reference is “analogous” is a question of fact. *Id* at 658.

Innovention argues that the Laser Chess articles are non-analogous art because the ’242 patent’s inventors were concerned with making a non-virtual, three-dimensional, laser-based board game, a project that involves mechanical engineering and optics, not computer programming. The district court appears to have agreed, finding that the Laser Chess references were non-analogous art since each discloses “an electronic version of the ’242 patent.” The court, however, failed to consider whether a reference disclosing an electronic laser-based strategy game, even if not in the same field of endeavor, would nonetheless have been reasonably pertinent to the problem facing an inventor of a new physical laser-based strategy game. In this case, the district court clearly erred in not finding the Laser Chess references to be analogous art based on this test as a matter of law.

The ’242 patent and the Laser Chess references are directed to the same purpose: detailing the specific game elements comprising a chess-like, laser-based strategy game. Specifically, the ’242 patent describes (1) the game’s components, including the game board and various types of playing pieces; (2) the game’s specific rules, including how the pieces may move on the game board during a player’s turn; and (3) the game’s ultimate objective, namely, illuminating an opponent’s key playing piece with a laser beam. The specification even distinguishes prior art patents based on these game elements, stating that U.S. Patent 3,516,671 lacks “the unique elements and rules of the [’242 patent’s] invention,” and U.S. Patent 6,702,286 contemplates a game in which the objective is not to “illuminate playing pieces,” but rather “to maneuver one’s pieces to flank (or surround) those of the opposing player.”

The Laser Chess references likewise describe specific playing pieces, rules, and objectives to create a chess-like, laser-based strategy game. Both Laser Chess and Advanced Laser Chess disclose, for example, (1) various game pieces, each with
Accordingly, the ‘242 patent and the Laser Chess references relate to the same goal: designing a winnable yet entertaining strategy game. The ‘242 patent’s specification confirms that game design was one objective facing its inventors. In particular, the specification states that “[s]trategy games may differ in a variety of ways,” such as in board layout, the number and types of playing pieces, and the manner in which each piece moves on the game board, and that “[e]ach of these variations affects the strategy of the play and the degree of skill required to play the game.” The specification thus admonishes that if the game elements “are overly simplistic, the game is too easy, will usually end in a draw or a predictable manner, and quickly become uninteresting for the average player.” Conversely, according to the specification, if the game elements “are overly complicated, the game takes too long to learn [and] is frustrating and uninteresting for the average player.”

The specific combination of game elements disclosed and claimed in the ‘242 patent thus deals with the problem of game design, and game elements from any strategy game, regardless how implemented, “logically would have commended itself to an inventor’s attention in considering [this] problem.” Clay, 966 F.2d at 659. Basic game elements remain the same regardless of the medium in which they are implemented: whether molded in plastic by a mechanical engineer or coded in software by a computer scientist. And, as MGA’s evidence shows, inventors of numerous prior art patents contemplated the implementation of their strategy games in both physical and electronic formats. For example, the Swift patent states that “[a]lthough the preferred embodiment is played by two players, obvious modifications of the game allow for *** a single player playing against a computer.” Swift patent, col. 2, ll. 47-51. Thus, because no reasonable jury could find that the Laser Chess references do not qualify as analogous prior art, and the district court erred in not so concluding as a matter of law.

Because of its error, the district court failed to properly consider the scope and content of the relevant prior art as well as the differences between that art and the claimed invention, including whether one of ordinary skill in the art would have been motivated to combine the teachings of the Laser Chess references with the Swift patent in light of the standard articulated in KSR International Co. v. Teleflex, Inc., 550 U.S. 398 (2007). We therefore remand these factual determinations to the district court to consider in the first instance. Furthermore, should the district court conclude that MGA has made out a prima facie case of obviousness based on the Laser Chess articles and the Swift patent, the court must then determine whether Innovation’s secondary considerations overcome MGA’s prima facie case.

B. Level of Skill in the Art

A determination of obviousness requires a factual finding of the level of ordinary skill in the art. 35 U.S.C. § 103(a); Graham, 383 U.S. at 17. Yet, a district court’s failure to make a correct finding on the level of skill constitutes reversible error only where it affects the ultimate conclusion under § 103. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 963 (Fed. Cir. 1986). For example, no reversal is necessary where a district court makes a determination that an inven-
tion would have been obvious to one having the lowest level of skill, i.e., a layperson, because what is obvious to a layperson is necessarily obvious to one with a higher level of skill in the field of the invention. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1574 (Fed. Cir. 1986), overruled on other grounds by *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc). Conversely, no reversal is necessary where a district court makes a determination of nonobviousness based on a finding of the highest possible level of skill in the relevant art, as fewer inventions are obvious to a person with a lower level of skill than to one with a higher level of skill. *Id.* A less sophisticated level of skill generally favors a determination of nonobviousness, and thus the patentee, while a higher level of skill favors the reverse. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1573 (Fed. Cir. 1984).

In this case, the district court found that MGA had failed to provide any evidence of the level of skill in the art, and thus concluded that MGA’s obviousness argument could be pursued only on the basis of what is obvious to a layperson. In so concluding, the district court erred. While MGA is permitted to argue that any level of skill, and thus the skill of a layperson, would suffice to support a holding of obviousness, the factual record in this case does not support such a finding. Here, Innovention conceded to the district court that the level of ordinary skill in the art was greater than that of a layperson. Specifically, Innovention asserted that the development of a three-dimensional game would not, in fact, be easy for the average layperson, as it took Innovention’s game creators, a Ph.D. in mechanical engineering and two mechanical engineering students, a year and a half to develop and finalize Innovention’s game, and that Innovention’s patent reveals that the claimed invention requires an understanding of geometrical optics. The district court appeared to agree, stating that “it seems some knowledge of mechanical engineering or optics is required.” The district court thus clearly erred in basing its obviousness analysis on what would have been obvious to a layperson notwithstanding evidence in the record and its apparent factual finding that one of ordinary skill in the art would possess a higher level of skill in the art.

Because the district court found nonobviousness based on an inappropriately low level of skill in the art, the error was not harmless. *Kloster*, 793 F.2d at 1574. Accordingly, on remand, the district court must make a finding on the level of skill in the art and base its obviousness analysis on that level of skill.

...  

In re Klein.

647 F.3d 1343 (Fed. Cir. 2011)

Schall, Judge:

Arnold G. Klein appeals the final decision of the Board ... affirming the rejection of certain claims of U.S. Patent Application No. 10/200,747 as obvious under 35 U.S.C. § 103. Because the Board’s finding that five references at issue are analogous art is not supported by substantial evidence, the obviousness rejections cannot be sustained and, accordingly, we reverse.
Background

I. Mr. Klein filed the '747 application, titled “Convenience Mixing and Storage Devices,” on July 24, 2002. The '747 application concerns a mixing device for use in preparation of sugar-water nectar for certain bird and butterfly feeders. According to the specification, the device has a series of rails that, when engaged with a divider, allow for the creation of two compartments for separating sugar and water within the device. The rails are located to divide the device into proportionate volumes of one part sugar to four parts water (to make hummingbird nectar), one part sugar to six parts water (to make oriole nectar), and one part sugar to nine parts water (to make butterfly nectar). Once the respective compartments have been filled to the same level with sugar and water, the divider is removed, allowing the sugar and water to mix and be stirred. The specification does not suggest that the sugar to water ratios are novel, instead disclosing in the “Background of the Invention” that these ratios are “currently recognized as being proportionally equivalent in sugar content as the birds, and butterflies [sic] natural nectar food sources.”

Figures 1, 2A-2B, and 4 of the '747 application, shown below, illustrate device 11, divider 21, and rails 15, 16, and 17.[

The sole independent claim at issue, claim 21, recites:

A convenience nectar mixing device for use in preparation of sugar-water nectar for feeding hummingbirds, orioles or butterflies, said device comprising:

a container that is adapted to receive water,

receiving means fixed to said container, and

a divider movably held by said receiving means for forming a compartment within said container, wherein said compartment has a volume that is proportionately less than a volume of said container, by a ratio established for the formulation of sugar-water nectar for hummingbirds, orioles or butterflies, wherein said compartment is adapted to receive sugar, and wherein removal of said divider from said receiving means allows mixing of said sugar and water to occur to provide said sugar-water nectar.

The remaining claims at issue, claims 22-25, 29, and 30, each depend from claim 21.

In a final rejection dated September 24, 2007, the examiner made five separate rejections under 35 U.S.C. § 103(a) [, each one involving a combination of one prior art reference and “the prior art sugar to water ratios discussed in the Klein specification.” Those five prior art references, all U.S. patents, are as follows: U.S. Patent No. 580,899 to Roberts; U.S. Patent No. 1,523,136 to O’Connor; U.S.
Mr. Klein appealed the final rejection to the Board.

II.

The Board affirmed each of the five obviousness rejections. The Board described Roberts, O’Connor, Kirkman, Greenspan, and De Santo as each “teach[ing] a device with a container having a movable divider held in place by a ‘receiving means,’ such as slots, grooves, or threads, which could be used to divide ingredients in specific ratios.” In addition, the Board pointed to the Klein specification’s own statement that the sugar-water ratios were known. According to the Board, “[t]hose of skill in the art would have had reason to use the known ratios with the available containers having movable dividers to achieve the correct proportions of water and sugar and to mix the ingredients for different nectars.” The Board rejected Mr. Klein’s argument that the five cited references are non-analogous art. In doing so, the Board found that the prior art was properly relied upon by the examiner because it is reasonably pertinent to the problem Mr. Klein addresses, which the Board found to be “making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals.”

Mr. Klein appealed. …

Discussion

… The Board’s determination that a prior art reference is analogous art presents an issue of fact, reviewed for substantial evidence. In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1378 (Fed. Cir. 2007).

I.

On appeal, Mr. Klein argues that the Board erred when it summarily concluded that the five cited references are “reasonably pertinent to the problem addressed by Klein.” Although the Board made a finding of fact as to the particular problem that Mr. Klein was addressing, specifically, “making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals,” Mr. Klein contends that the Board failed to make any finding that any of the cited references are “reasonably pertinent” to that problem. Further, Mr. Klein argues, the Board identified no evidence that suggests that an inventor seeking to solve the problem Mr. Klein was addressing, which Mr. Klein characterizes as a “multiple ratio mixing problem,” would look to any of the references to address the problem of preparing different ratios.

The government responds that the Board correctly found that the prior art references were directed toward the same problem Mr. Klein sought to solve with his device, which the government characterizes as a “compartment separation problem.” Because “[t]he problem of keeping things separated is not unique to nectar mixing and storage devices,” and “nothing about the prior art containers with adjustable, removable dividers is unique to their particular applications,” the government contends that “[o]ne confronted with Klein’s desire to keep two ingredients separated and also allow for them to be mixed together would have readily consult-
ed these references to discover the broad solution therein … and applied it to his particular application … .”

II.

A reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention. In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004); In re Clay, 966 F.2d 656, 658 (Fed. Cir. 1992). “Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” Bigio, 381 F.3d at 1325. Here, the Board focused exclusively on the “reasonably pertinent to the particular problem” test. “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” Clay, 966 F.2d at 659. “If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection.” Id.

Mr. Klein does not challenge the Board’s factual finding of the problem he was addressing, namely “making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals.” Mr. Klein argues, however, that Roberts, O’Connor, Kirkman, Greenspan, and De Santo are each directed to a wholly different problem than the one he faced. We examine each reference in turn.

Roberts is directed to an “Apparatus for Keeping Accounts.” The apparatus of Roberts includes receptacles, such as receptacles 1 and 2 (shown in dotted lines in Figure 1 [to the right]), having a “series of vertical channels 11, adapted to receive removable partitions 12, by means of which the receptacles may be subdivided into compartments.” Roberts patent. According to Roberts, the receptacles are “designed to receive statement-cards,” and each includes a hand-hole 10 to assist in removing the receptacle from a drawer. …

O’Connor is directed to a tool tray having dividers that are “readily movable” and that is “adapted to contain comparatively small articles, for example, drills, reamers, bits, etc., or hardware supplies such as bolts, nuts and the like.” O’Connor patent. As shown in Figure 1 of O’Connor, reproduced [at right], divider 8 is not positioned flush with the bottom of the tray[.]
Kirkman is directed to a “Plastic Cabinet Drawer with Removable Partitions.” Kirkman explains that it “relates to drawers for relatively small cabinets for containing various types of small articles, and more particularly to a drawer of this type provided with removable partitions or dividers, for dividing the drawer into two or more compartments of varying size, with means for frictionally holding the partitions in adjusted position [sic] within the drawer.” Kirkman patent. As shown in Figure 1 of Kirkman [at left], the lower edge of partition 9 has a small notch.

Mr. Klein argues that, consistent with the Board’s own express findings, Roberts, O’Connor, and Kirkman are each directed to a container designed to separate its contents, as opposed to one designed to facilitate the mixing of those contents. Mr. Klein also argues that, in view of (1) the hand-hole 10 of Roberts, (2) how divider 8 of O’Connor is positioned to not be flush with the bottom of the tray, and (3) the notch in the lower edge of partition 9 of Kirkman, none of these three references is “adapted to receive water,” as is required by claim 21 of the ’747 application.

We agree with Mr. Klein that the Board’s conclusory finding that Roberts, O’Connor, and Kirkman are analogous is not supported by substantial evidence. The purpose of each of Roberts, O’Connor, or Kirkman is to separate solid objects. An inventor considering the problem of “making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals,” would not have been motivated to consider any of these references when making his invention, particularly since none of these three references shows a partitioned container that is adapted to receive water or contain it long enough to be able to prepare different ratios in the different compartments. See Clay, 966 F.2d at 659 (“If [a reference] is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.”).  

1 We agree with Mr. Klein that, to the extent the government attempts to do so, it cannot redefine the problem Mr. Klein was addressing as a “compartment separation problem” on appeal. See Sec. & Exch. Comm’n v. Chenery Corp., 318 U.S. 80, 94 (1943) (“[A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained.”).
Turning to the remaining two references, Greenspan is directed to a “Blood Plasma Bottle” having a compartment for dried plasma and a compartment for water, where the compartments are separated by a “wall which is normally plugged during transportation of the bottle.” Greenspan col. 2, ll. 12-17. When the plasma is going to be used, the plasma compartment is unplugged, the plug becomes the cap for the bottle, and the bottle is shaken to dissolve the plasma. As shown in Figure 2 of Greenspan, [to the right], the wall 24 cannot be moved to adjust the relative sizes of the lower (plasma) compartment 30 or upper (water) compartment 28[.]

De Santo’s “Fluid Container” has two compartments designed to hold two different types of fluid, which can be “rapidly and thoroughly mixed together at the desired time without opening the container externally” to make, for example, hair rinses. De Santo col. 1, ll. 8-17, 23-28. Compartments 24 and 26 are separated by partition 28, which is “provided with a central opening 32 defining an annular valve seat 34 which is engageable with a valve member 36 to open and close the partition as desired.” As shown [at left] in Figure 5, partition 28 is in a fixed location.

Greenspan and De Santo are not analogous, Mr. Klein argues, because they do not address multiple ratios or have a “movable divider.” We agree. While Greenspan and De Santo are each directed to containers that facilitate the mixing of two separated substances together, an inventor considering the problem of “making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals,” would not have been motivated to consider either of these references since neither of the references shows a movable divider or the ability to prepare different ratios.² (Emphasis added). In [its d]ecision, the Board did not set forth any reasoning in support of its finding that Greenspan and De Santo are analogous, and thus, this finding is also not supported by substantial evidence.

For the foregoing reasons, we reverse the decision of the Board. The case is remanded to the Board for further proceedings consistent with this opinion.

Editor’s Note
Klein ultimately did receive his patent, U.S. Patent No. 8,147,119.

² As noted above, we agree with Mr. Klein that the government cannot now redefine the problem Mr. Klein was addressing as a “compartment separation problem.”
K-TEC, Inc. v. Vita-Mix Corp.
696 F.3d 1364 (Fed. Cir. 2012)

Lourie, Judge:

Vita-Mix Corporation ("Vita-Mix") appeals from the district court’s final judgment in which the court concluded that ... that two prior art references were not analogous art for the purposes of an obviousness analysis [and] that substantial evidence supported the jury’s findings that the asserted claims were not proved invalid .... On appeal, Vita-Mix challenges those conclusions in addition to other rulings made by the district court during trial. Because the district court did not err in any respect and the jury’s findings were properly supported, we affirm.

Background

I. This patent case relates to commercial blenders that are used to make blended beverages. K-TEC, a company that manufactures and sells commercial blending equipment, owns U.S. Patents 6,979,117 and 7,281,842, which generally disclose and claim a blending system that contains a blending jar with a specific geometry. The benefit of the claimed geometry is that it alters the flow pattern of the liquid during blending in a way that reduces cavitation, which occurs when a pocket of air envelops the area surrounding the blender blade during blending. '842 patent, col. 2, ll. 11-15; col. 7, ll. 4-14.

The two patents are related—the '117 patent is the parent of the '842 patent. Claim 1 of the '842 patent is representative for the purposes of this appeal. It claims a “blending jar” that comprises “four side walls” and a “fifth truncated wall” arranged in a specific geometry:

1. A blending jar apparatus, comprising:
   a blending jar having a blending element which rotates on a central axis, the jar to hold at least one foodstuff to be blended, the blending jar comprising:
   a bottom wall;
   four side walls extending from the bottom wall, the four side walls defining an opening having a generally rectangular shape, the opening being configured to receive the at least one foodstuff;
   a fifth truncated wall disposed between two of the four side walls;
   a handle secured to the blending jar adjacent to the fifth truncated wall;
   wherein the fifth truncated wall is positioned closer to the central axis than corners formed by the four side walls.
The written description details the claimed geometry. In particular, Figure 11, reproduced below, depicts the claimed jar, with four side walls, labeled 132, 134, 136, and 138, and a fifth truncated wall, labeled 135.

In the ... figure, the fifth truncated wall is disposed between side walls 138 and 132 and is positioned closer to the blending jar’s central axis 144 than the corners formed by the four side walls. The written description explains that the fifth wall “truncates, in essence, the typical corner that would otherwise be formed between wall 132 and 138.” Similarly, K-TEC explained to the [PTO] that the truncated wall “may be planar or curved, as long as it truncates a typical corner that would otherwise be formed if the truncated wall were not present.” The corners created by the sidewalls “may be formed at generally right angles,” although the specification depicts them also as rounded.

As a result of this geometry, the vortex created when blending liquid inside the container moves away from the central axis and toward the truncated wall. The shifted vortex creates a flow pattern in which, during blending, the liquid will climb up the corner opposite the truncated wall and will be lower at the truncated wall. That flow pattern reduces cavitation in the container, increasing the speed and efficiency with which smoothies and other beverages can be made.

K-TEC and Vita-Mix compete in the market for commercial blenders. In 2001, K-TEC began selling a five-sided blending jar that was an embodiment of the ’117 and ’842 patents’ claims. After K-TEC acquired a number of customers in 2001 and 2002, Vita-Mix began to consider upgrading its existing four-sided container. In that process, its “example” design was K-TEC’s five-sided container. Although Vita-Mix attempted different design changes, it introduced its new MP container in May 2003, a design that Vita-Mix personnel admitted was a copy of K-TEC’s five-sided container.

After Vita-Mix released the MP container, K-TEC notified Vita-Mix in March 2005 that the container infringed the parent patent of the ’117 and ’842 patents. In late 2005, one of K-TEC’s employees notified Vita-Mix personnel that the ’117 patent would soon issue and that Vita-Mix’s MP container would infringe that patent. The day after the patent issued, the record shows that Vita-Mix’s CEO knew that “the K-Tec patent for the MP container” had issued.

II.

Shortly after the ’117 patent issued, K-TEC sued Vita-Mix ... alleging that the MP container infringed a number of claims of the ’117 patent. Thereafter, K-TEC amended its complaint to include the ’842 patent and the [Vita-Mix] XP container. Ultimately, K-TEC pursued damages only for sales of the XP container.
During the proceedings, the district court ... granted K-TEC’s motion for summary judgment that the XP container infringed the asserted claims and partially granted K-TEC’s motion that the asserted claims are not invalid. ... In partially granting K-TEC’s motion upholding the validity of the ’117 and ’842 patents, the court concluded that Vita-Mix had failed to raise a genuine issue of material fact that [the] two nonblender designs [shown below] that depict five-sided containers, U.S. Design Patents 163,117 ("Hobbs") and 227,535 ("Grimes"), would have been reasonably pertinent to solving the cavitation problem that the ’117 and ’842 patents’ inventor faced when he conceived those inventions.

... 

In 2010, the parties tried the remaining invalidity, willfulness, and damages issues to a jury, which found in favor of K-TEC on all issues. ...

Discussion

... 

III. 

... Vita-Mix argues that the district court erred in granting summary judgment that Grimes and Hobbs are not analogous art. To support its argument that those references were reasonably pertinent art, Vita-Mix points to the inventor’s deposition testimony that the problems he confronted during the development of the patented jar included designing a jar that would fit within a particular dimension. Vita-Mix also points to its expert’s report on invalidity. Finally, Vita-Mix points to the PTO’s reexamination of the ’117 patent, in which the Board held that Hobbs and Grimes were analogous art.

K-TEC responds that the ornamental designs of containers had no bearing on the inventor’s cavitation problem, a problem specific to the field of blenders. K-TEC
argues that the size of the container and the jar’s hand clearance were not problems in the prior art. Finally, K-TEC argues that even if Hobbs and Grimes are analogous prior art, inclusion of those references would not have had a material effect on the district court’s determination of obviousness.

We agree with K-TEC that the district court properly granted summary judgment that Grimes and Hobbs are not analogous art. To qualify as prior art for an obviousness analysis, a reference must qualify as “analogous art,” i.e., it must satisfy one of the following conditions: (1) the reference must be from the same field of endeavor; or (2) the reference must be reasonably pertinent to the particular problem with which the inventor is involved. Innovention Toys, LLC v. MGA Entm’t, Inc., 637 F.3d 1314, 1321 (Fed. Cir. 2011). A reference is reasonably pertinent if it, as a result of its subject matter, “logically would have commended itself to an inventor’s attention in considering his problem.” Id.

Here, Vita-Mix does not dispute that Hobbs and Grimes are not in the same field of endeavor as the ’117 and ’842 patents. However, Vita-Mix also failed to raise a genuine issue of material fact that the references would have been reasonably pertinent the inventor in considering his problem.

First, the inventor’s testimony, by itself, failed to raise a genuine issue of material fact that Hobbs and Grimes would have been considered reasonably pertinent art. According to the specification, there are four prior art problems that the invention solves: blender speed, safety, cavitation, and the blender’s ability to blend frozen ingredients. Consistent with that description, the inventor testified that he sought to create a blending jar that “would reduce or prevent cavitation when blending frozen drinks.” While the inventor’s testimony also mentioned that, in developing the patented jar, he also wanted the resulting jar to fit within K-TEC’s existing quiet box, there is no dispute that creating a smaller jar was not the problem he set out to solve because K-TEC’s existing jars already fit within the quiet box. Thus, the inventor’s testimony does not raise a genuine issue of material fact.

Second, Vita-Mix’s expert’s report on invalidity failed to raise a genuine issue of material fact because, as the district court correctly concluded, the report was “silent on the question of why [the inventor] would have looked to non-blending containers to discover the[ ] commonplace designs” depicted in Hobbs and Grimes. Indeed, the report did not address the Grimes reference. Ultimately, the district court rightly concluded that the report did not “explain any rational underpinning for [the inventor] to have consulted non-blending containers or food mixers in order to solve the problems he encountered in designing a new blending container,” and properly concluded that the report failed to raise a genuine issue of material fact.

Finally, the Board’s decision that Hobbs and Grimes were analogous art does not raise a genuine issue of material fact. As an initial matter, the district court did not have the benefit of the Board’s [reexamination] analysis because the Board’s opinion did not issue until well after the district court entered final judgment in this case. But, regardless whether we consider such post-judgment events in this appeal, see Marine Polymer Techs., Inc. v. HemCon, Inc., 672 F.3d 1350, 1362 (Fed. Cir. 2012) (en banc), summary judgment was appropriate in this case. Here, it was Vita-Mix’s burden before the district court to proffer evidence such that a reasonable ju-
ror could find the ’117 and ’842 patents invalid under the clear and convincing standard of proof. As recounted above, Vita-Mix failed to meet that burden.

Biochemical Cases

Takeda Chemical Indus. v. Alphapharm Pty., Ltd.
492 F.3d 1350 (Fed. Cir. 2007)

Lourie, Judge:

Alphapharm Pty., Ltd. and Genpharm, Inc. (collectively “Alphapharm”) appeal from the decision ... following a bench trial that U.S. Patent 4,687,777 was not shown to be invalid under 35 U.S.C. § 103. Because we conclude that the district court did not err in determining that the claimed compounds would not have been obvious in light of the prior art, and hence that the patent has not been shown to be invalid, we affirm.

Background

Diabetes is a disease that is characterized by the body’s inability to regulate blood sugar. It is generally caused by inadequate levels of insulin—a hormone produced in the pancreas. Insulin allows blood sugar or glucose, which is derived from food, to enter into the body’s cells and be converted into energy. There are two types of diabetes, known as Type 1 and Type 2. In Type 1 diabetes, the pancreas fails to produce insulin, and individuals suffering from this type of diabetes must regularly receive insulin from an external source. In contrast, Type 2 diabetic individuals produce insulin. However, their bodies are unable to effectively use the insulin that is produced. This is also referred to as insulin resistance. As a result, glucose is unable to enter the cells, thereby depriving the body of its main source of energy. Type 2 diabetes is the most common form of diabetes—affecting over 90% of diabetic individuals.

In the 1990s, a class of drugs known as thiazolidinediones (“TZDs”) was introduced on the market as a treatment for Type 2 diabetes. Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc. (collectively “Takeda”) first invented certain TZDs in the 1970s. Takeda’s research revealed that TZDs acted as insulin sensitizers, i.e., compounds that ameliorate insulin resistance. Although the function of TZDs was not completely understood, TZDs appeared to lower blood glucose levels by binding to a molecule in the nucleus of the cell known as PPAR-gamma, which activates insulin receptors and stimulates the production of glucose transporters. The transporters then travel to the cellular surface and enable glucose to enter the cell from the bloodstream.

Takeda developed the drug ACTOS, which is used to control blood sugar in patients who suffer from Type 2 diabetes. ACTOS has enjoyed substantial commercial success since its launch in 1999. By 2003, it held 47% of the TZD market, and gross sales for that year exceeded $1.7 billion. The active ingredient in ACTOS is the TZD compound pioglitazone, a compound claimed in the patent in suit.
Takeda owns the ’777 patent, entitled “Thiazolidinedione Derivatives, Useful As Antidiabetic Agents.” The patent is directed to “compounds which can be practically used as antidiabetic agents having a broad safety margin between pharmacological effect and toxicity or unfavorable side reactions.” ’777 patent, col. 1, ll. 34-37. The asserted claims are claims 1, 2, and 5. Claim 1 claims a genus of compounds. Claim 5 claims pharmaceutical compositions containing that genus of compounds. Those claims read as follows:

1. A compound of the formula:

![Chemical Structure](image)

or a pharmacologically acceptable salt thereof.

5. An antidiabetic composition which consists essentially of a compound of the formula:

![Chemical Structure](image)

or a pharmacologically acceptable salt thereof, in association with a pharmacologically acceptable carrier, excipient, or diluent.

For purposes of this appeal, the critical portion of the compound structure is the left moiety[†] of the molecule, namely, the ethyl-substituted pyridyl ring.¹ That chemical structure, which has an ethyl substituent (C₂H₅) pictorially drawn to the center of the pyridyl ring, indicates that the structure covers four possible compounds, viz., compounds with an ethyl substituent located at the four available positions on the pyridyl ring. The formula includes the 3-ethyl compound, 4-ethyl compound, 5-ethyl compound (pioglitazone), and 6-ethyl compound.

Claim 2 of the ’777 patent covers the single compound pioglitazone. … Pioglitazone is referred to as the 5-ethyl compound because the ethyl substituent is attached to the 5-position on the pyridyl ring. That portion of the compound is depicted as:

![Chemical Structure](image)

Alphapharm, a generic drug manufacturer, filed an Abbreviated New Drug Application (“ANDA”) seeking [FDA] approval to manufacture and sell a generic version of pioglitazone. Alphapharm filed an appropriate certification with its ANDA asserting that the ’777 patent is invalid as obvious under 35 U.S.C. § 103. In response, Takeda sued Alphapharm, along with three other generic drug

† [ Ed. Note—In chemical parlance, a “moiety” is simply a molecule portion, which may contain whole functional groups or parts of functional groups. ]

¹ Pyridine is a six-membered carbon-containing ring with one carbon replaced by a nitrogen.
manufacturers who [had] also sought FDA approval to market generic pioglitazone, alleging that the defendants have infringed or will infringe the ’777 patent.

On January 17, 2006, the district court commenced a bench trial solely on the issues of validity and enforceability of the ’777 patent. Alphapharm advanced its invalidity argument, asserting that the claimed compounds would have been obvious at the time of the alleged invention. Alphapharm’s obviousness contention rested entirely on a prior art TZD compound that is referenced in Table 1 of the ’777 patent [itself] as “compound b.” The left moiety of compound b consists of a pyridyl ring with a methyl (CH3) group attached to the 6-position of the ring. That portion of its chemical structure is illustrated as follows:

![Chemical Structure](attachment:image.png)

Alphapharm asserted that the claimed compounds would have been obvious over compound b.

The district court found that Alphapharm failed to prove by clear and convincing evidence that the asserted claims were invalid as obvious under 35 U.S.C. § 103. The court first concluded that there was no motivation in the prior art to select compound b as the lead compound for antidiabetic research, and that the prior art taught away from its use. As such, the court concluded that Alphapharm failed to make a prima facie case of obviousness. The court continued its analysis and found that even if Alphapharm succeeded in making a prima facie showing, Takeda would still prevail because any prima facie case of obviousness was rebutted by the unexpected results of pioglitazone’s nontoxicity. The court then rendered judgment in favor of Takeda. …

…

Discussion

B. Obviousness

Alphapharm … asserts that the district court misapplied the law, particularly the law governing obviousness in the context of structurally similar chemical compounds. According to Alphapharm, the record established that compound b was the most effective antidiabetic compound in the prior art, and thus the court erred by failing to apply a presumption that one of ordinary skill in the art would have been motivated to make the claimed compounds. Alphapharm asserts that such a conclusion is mandated by our case law, including our en banc decision in In re Dillon, 919 F.2d 688 (Fed. Cir. 1990). …

Takeda responds that the district court correctly determined that Alphapharm failed to prove by clear and convincing evidence that the asserted claims are invalid as obvious. Takeda contends that there was overwhelming evidence presented at trial to support the court’s conclusion that no motivation existed in the prior art for one of ordinary skill in the art to select compound b as a lead compound, and even if there was, that the unexpected results of pioglitazone’s improved toxicity would have rebutted any prima facie showing of obviousness. …
We agree with Takeda that the district court did not err in concluding that the asserted claims of the ’777 patent would not have been obvious. The Supreme Court recently addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Court stated that the *Graham v. John Deere Co.*, 383 U.S. 1 (1966), factors still control an obviousness inquiry. …

In a thorough and well-reasoned opinion, albeit rendered before *KSR* was decided by the Supreme Court, the district court made extensive findings of fact and conclusions of law as to the four *Graham* factors. Alphapharm’s arguments challenge the court’s determinations with respect to certain of these factors, which we now address.

1. Differences Between the Prior Art and the Claims
   a. *Selection of Compound b as Lead Compound*—Alphapharm’s first argument challenges the court’s determination with regard to the “differences between the prior art and the claims.” Alphapharm contends that the court erred as a matter of law in holding that the ethyl-substituted TZDs were nonobvious in light of the closest prior art compound, compound b, by misapplying the law relating to obviousness of chemical compounds.

   We disagree. Our case law concerning *prima facie* obviousness of structurally similar compounds is well-established. We have held that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.” *Dillon*, 919 F.2d at 692. In addition to structural similarity between the compounds, a *prima facie* case of obviousness also requires a showing of “adequate support in the prior art” for the change in structure. *In re Grabiak*, 769 F.2d 729, 731-32 (Fed. Cir. 1985).

   We elaborated on this requirement in the case of *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995), where we stated that “[n]ormally a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound.” That is so because close or established “[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.” *Id.* A known compound may suggest its homolog, analog, or isomer because such compounds “often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.” *Id.* We clarified, however, that in order to find a *prima facie* case of unpatentability in such instances, a showing that the “prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention” was also required. *Id.* (citing *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *Dillon*, 919 F.2d 688; *Grabiak*, 769 F.2d 729; *In re Lalu*, 747 F.2d 703 (Fed. Cir. 1984)).

   That test for *prima facie* obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*. While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the Court acknowledged the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the ele-
ments in the way the claimed new invention does” in an obviousness determination. KSR, 550 U.S. at 418. Moreover, the Court indicated that there is “no necessary inconsistency between the idea underlying the TSM test and the Graham analysis.” Id. at 419. As long as the test is not applied as a “rigid and mandatory” formula, that test can provide “helpful insight” to an obviousness inquiry. Id. Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.

We agree with Takeda and the district court that Alphapharm failed to make that showing here. Alphapharm argues that the prior art would have led one of ordinary skill in the art to select compound b as a lead compound. By “lead compound,” we understand Alphapharm to refer to a compound in the prior art that would be most promising to modify in order to improve upon its antidiabetic activity and obtain a compound with better activity.2 Upon selecting that compound for antidiabetic research, Alphapharm asserts that one of ordinary skill in the art would have made two obvious chemical changes: first, homologation, i.e., replacing the methyl group with an ethyl group, which would have resulted in a 6-ethyl compound; and second, “ring-walking,” or moving the ethyl substituent to another position on the ring, the 5-position, thereby leading to the discovery of pioglitazone. Thus, Alphapharm’s obviousness argument clearly depends on a preliminary finding that one of ordinary skill in the art would have selected compound b as a lead compound.

The district court found, however, that one of ordinary skill in the art would not have selected compound b as the lead compound. In reaching its determination, the court first considered Takeda’s U.S. Patent 4,287,200, which was issued on September 1, 1981, and its prosecution history. The court found that the ’200 patent “discloses hundreds of millions of TZD compounds.”3 The patent specifically identified fifty-four compounds, including compound b, that were synthesized according to the procedures described in the patent, but did not disclose experimental data or test results for any of those compounds. The prosecution history, however, disclosed test results for nine specific compounds, including compound b. That information was provided to the examiner in response to a rejection in order to show that the claimed compounds of the ’200 patent were superior to the known compounds that were disclosed in a cited reference. The court, however, found nothing in the ’200 patent, or in its file history, to suggest to one of ordinary skill in the art that those nine compounds, out of the hundreds of millions of compounds covered by the

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2 The parties do not dispute that compound b was the closest prior art compound. Thus, the legal question is whether or not the claimed subject matter would have been obvious over that compound. We will, however, use Alphapharm’s terminology of “lead compound” in this opinion, deciding the appeal as it has been argued.

3 Three divisional applications derive from the ’200 patent. Those applications matured into U.S. Patent 4,340,605; U.S. Patent 4,438,141; and U.S. Patent No. 4,444,779. The ’779 patent is of particular relevance in this appeal and is discussed below.
patent application, were the best performing compounds as antidiabetics, and hence targets for modification to seek improved properties.

The court next considered an article that was published the following year in 1982 by T. Sodha et al. entitled “Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl-]thiazolidine-2,4-dione (ADD-3878) and Its Derivatives” (“Sodha II”). The Sodha II reference disclosed data relating to hypoglycemic activity and plasma triglyceride lowering activity for 101 TZD compounds. Those compounds did not include pioglitazone, but included compound b. Significantly, Sodha II identified three specific compounds that were deemed most favorable in terms of toxicity and activity. Notably, compound b was not identified as one of the three most favorable compounds. On the contrary, compound b, was singled out as causing “considerable increases in body weight and brown fat weight.”

The court also considered Takeda’s ‘779 patent. That patent covers a subset of compounds originally included in the ‘200 patent application, namely, TZD compounds “where the pyridyl or thiazolyl groups may be substituted.” The broadest claim of the ‘779 patent covers over one million compounds. Compound b was specifically claimed in claim 4 of the patent. The court noted that a preliminary amendment in the prosecution history of the patent contained a statement that “the compounds in which these heterocyclic rings are substituted have become important, especially [compound b].”

Based on the prior art as a whole, however, the court found that a person of ordinary skill in the art would not have selected compound b as a lead compound for antidiabetic treatment. Although the prosecution history of the ‘779 patent included the statement that characterized compound b as “especially important,” the court found that any suggestion to select compound b was essentially negated by the disclosure of the Sodha II reference. The court reasoned that one of ordinary skill in the art would not have chosen compound b, notwithstanding the statement in the ‘779 patent prosecution history, “given the more exhaustive and reliable scientific analysis presented by Sodha II, which taught away from compound b, and the evidence from all of the TZD patents that Takeda filed contemporaneously with the ‘779 [p]atent showing that there were many promising, broad avenues for further research.”

The court found that the three compounds that the Sodha II reference identified as “most favorable” and “valuable for the treatment of maturity-onset diabetes,” not compound b, would have served as the best “starting point for further investigation” to a person of ordinary skill in the art. Because diabetes is a chronic disease and thus would require long term treatment, the court reasoned that researchers would have been dissuaded from selecting a lead compound that exhibited negative effects, such as toxicity, or other adverse side effects, especially one that causes “considerable increases in body weight and brown fat weight.” Thus, the court determined that the prior art did not suggest to one of ordinary skill in the art that compound b would be the best candidate as the lead compound for antidiabetic research.
Admissions from Alphapharm witnesses further buttressed the court’s conclusion. Dr. Rosenberg, head of Alphapharm’s intellectual property department, testified as a [Fed. R. Civ. P.] 30(b)(6) witness on behalf of Alphapharm. In discussing Sodha II, Dr. Rosenberg admitted that there was nothing in the article that would recommend that a person of ordinary skill in the art choose compound b over other compounds in the article that had the same efficacy rating. Dr. Rosenberg, acknowledging that compound b had the negative side effects of increased body weight and brown fat, also admitted that a compound with such side effects would “presumably not” be a suitable candidate compound for treatment of Type 2 diabetes. Alphapharm’s expert, Dr. Mosberg, concurred in that view at his deposition when he admitted that a medicinal chemist would find such side effects “undesirable.”

Moreover, another Alphapharm 30(b)(6) witness, Barry Spencer, testified at his deposition that in reviewing the prior art, one of ordinary skill in the art would have chosen three compounds in Sodha II as lead compounds for research, not solely compound b. In addition, Takeda’s witness, Dr. Morton, testified that at the time Sodha II was published, it was known that obesity contributed to insulin resistance and Type 2 diabetes. Thus, one of ordinary skill in the art would have concluded that Sodha II taught away from pyridyl compounds because it associated adverse side effects with compound b.

We do not accept Alphapharm’s assertion that KSR, as well as another case recently decided by this court, Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007), mandates reversal. Relying on KSR, Alphapharm argues that the claimed compounds would have been obvious because the prior art compound fell within “the objective reach of the claim,” and the evidence demonstrated that using the techniques of homologation and ring-walking would have been “obvious to try.” Additionally, Alphapharm argues that our holding in Pfizer, where we found obvious certain claims covering a particular acid-addition salt, directly supports its position.

We disagree. The KSR Court recognized that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” KSR, 550 U.S. at 421. In such circumstances, “the fact that a combination was obvious to try might show that it was obvious under § 103.” Id. That is not the case here. Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was “obvious to try.” The evidence showed that it was not obvious to try.

Similarly, Alphapharm’s reliance on Pfizer fares no better. In Pfizer, we held that certain claims covering the besylate salt of amlodipine would have been obvious. The prior art included a reference, referred to as the Berge reference, that dis-
closed a genus of pharmaceutically acceptable anions that could be used to form pharmaceutically acceptable acid addition salts, as well as other publications that disclosed the chemical characteristics of the besylate salt. Pfizer, 480 F.3d at 1363. Noting that our conclusion was based on the “particularized facts of this case,” we found that the prior art provided “ample motivation to narrow the genus of 53 pharmaceutically-acceptable anions disclosed by [the] Berge [reference] to a few, including benzene sulphonate.” Id. at 1363, 1367. Here, the court found nothing in the prior art to narrow the possibilities of a lead compound to compound b. In contrast, the court found that one of ordinary skill in the art would have chosen one of the many compounds disclosed in Sodha II, of which there were over ninety, that “did not disclose the existence of toxicity or side effects, and to engage in research to increase the efficacy and confirm the absence of toxicity of those compounds, rather than to choose as a starting point a compound with identified adverse effects.” Thus, Pfizer does not control this case.

Based on the record before us, we conclude that the district court’s fact-findings were not clearly erroneous and were supported by evidence in the record. Moreover, we reject the assertion that the court failed to correctly apply the law relating to prima facie obviousness of chemical compounds. Because Alphapharm’s obviousness argument rested entirely on the court making a preliminary finding that the prior art would have led to the selection of compound b as the lead compound, and Alphapharm failed to prove that assertion, the court did not commit reversible error by failing to apply a presumption of motivation. We thus conclude that the court did not err in holding that Alphapharm failed to establish a prima facie case of obviousness. See Eli Lilly & Co. v. Zenith Goldline Pharms., 471 F.3d 1369 (Fed. Cir. 2006) (affirming the district court’s finding of nonobviousness upon concluding, in part, that the prior art compound would not have been chosen as a lead compound).

b. Choice of the Claimed Compounds—Even if Alphapharm had established that preliminary finding, and we have concluded that it did not, the record demonstrates that Alphapharm’s obviousness argument fails on a second ground. The district court found nothing in the prior art to suggest making the specific molecular modifications to compound b that are necessary to achieve the claimed compounds. In reaching that conclusion, the court first found that the process of modifying lead compounds was not routine at the time of the invention. Dr. Mosberg opined that the steps of homologation and ringwalking were “routine steps in the drug optimization process,” but the court found that testimony unavailing in light of the contrary, more credible, testimony offered by Takeda’s experts. In addition, the court relied on Dr. Rosenberg’s admission that a person of ordinary skill in the art would “look at a host of substituents, such as chlorides, halides and others, not just methyls” in modifying the pyridyl ring.

Pioglitazone differs from compound b in two respects, and one would have to both homologate the methyl group of compound b and move the resulting ethyl group to the 5-position on the pyridyl ring in order to obtain pioglitazone. With regard to homologation, the court found nothing in the prior art to provide a reasonable expectation that adding a methyl group to compound b would reduce or
eliminate its toxicity. Based on the test results of the numerous compounds disclosed in Sodha II, the court concluded that “homologation had no tendency to decrease unwanted side effects” and thus researchers would have been inclined “to focus research efforts elsewhere.” Indeed, several other compounds exhibited similar or better potency than compound b, and one compound in particular, compound 99, that had no identified problems differed significantly from compound b in structure. Moreover, Dr. Mosberg agreed with Takeda’s expert, Dr. Danishefsky, that the biological activities of various substituents were “unpredictable” based on the disclosure of Sodha II. The court also found nothing in the ’200 and ’779 patents to suggest to one of ordinary skill in the art that homologation would bring about a reasonable expectation of success.

As for ring-walking, the court found that there was no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes. Dr. Mosberg opined that the process of ring-walking was “known” to Takeda, but the court found that testimony inapt as it failed to support a reasonable expectation to one of ordinary skill in the art that performing that chemical change would cause a compound to be more efficacious or less toxic. Moreover, Dr. Mosberg relied on the efficacy data of phenyl compounds in Sodha II, but the court found those data insufficient to show that the same effects would occur in pyridyl compounds.

We thus conclude that Alphapharm’s challenges fail to identify grounds for reversible error. The court properly considered the teachings of the prior art and made credibility determinations regarding the witnesses at trial. We do not see any error in the district court’s determination that one of ordinary skill in the art would not have been prompted to modify compound b, using the steps of homologation and ring-walking, to synthesize the claimed compounds. Because the court’s conclusions are not clearly erroneous and are supported by the record evidence, we find no basis to disturb them.

The court properly concluded that Alphapharm did not make out a prima facie case of obviousness because Alphapharm failed to adduce evidence that compound b would have been selected as the lead compound and, even if that preliminary showing had been made, it failed to show that there existed a reason, based on what was known at the time of the invention, to perform the chemical modifications necessary to achieve the claimed compounds.

In light of our conclusion that Alphapharm failed to prove that the claimed compounds would have been prima facie obvious, we need not consider any objective indicia of nonobviousness.

We have considered Alphapharm’s remaining arguments and find none that warrant reversal of the district court’s decision.
Hoffmann-La Roche Inc. v. Apotex Inc.
748 F.3d 1326 (Fed. Cir. 2014)

Bryson, Judge:

Plaintiff Hoffmann-La Roche, Inc., appeals from the decision ... granting the defendant generic drug companies summary judgment of invalidity as to claims 1-8 of U.S. Patent No. 7,718,634 and claims 1-10 of U.S. Patent No. 7,410,957. We affirm.

I

The patents at issue in this appeal are directed to methods of treating osteoporosis through the once monthly administration of ibandronate, one of a class of compounds known as bisphosphonates. Ibandronate, a salt of ibandronic acid, is commercially available as Roche’s once monthly Boniva, which was approved by the FDA in 2005 for the treatment of osteoporosis. Once monthly Boniva provides a 150 mg dose of ibandronate.

Osteoporosis is a disease characterized by abnormal bone resorption. Resorption, the biological process by which bone is broken down, causes decreased bone strength and an increased risk of fractures. Bisphosphonates are “potent inhibitors of bone resorption.” ‘957 patent, col. 1, ll. 39-40. They inhibit abnormal bone destruction and enable the gradual restoration of lost bone mineral density (“BMD”).

Bisphosphonates are generally known to have a low bioavailability when administered orally, i.e., only a small fraction of a given dose is absorbed into the blood. Additionally, oral administration of bisphosphonates can result in adverse esophageal and gastrointestinal side effects. As a result of the side effects and to improve the bioavailability of the drug, patients taking bisphosphonates must adhere to a dosing regimen that requires a bisphosphonate tablet to be taken in a fasting state at least 30 minutes before eating or drinking. In the past, the inconvenience of that regimen created problems of patient compliance. Researchers in the field believed that less-frequent dosing would result in patients continuing the treatment for the long term, which is required for bisphosphonate treatments to be successful.

Roche owns the ‘634 patent and the ‘957 patent, which is the parent of the ‘634 patent. Claims 1-8 of the ‘634 patent and claims 1-10 of the ‘957 patent are at issue in this case and describe a method of treating osteoporosis consisting of orally administering about 150 mg of ibandronic acid once monthly on a single day. Claim 1 of the ‘634 patent is representative of the claims on appeal:

1. A method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of ibandronic acid, comprising:

(a) commencing the administration of the pharmaceutically acceptable salt of ibandronic acid by orally administering to the postmenopausal woman, on a single day, a first dose in the form of a tablet, wherein the tablet comprises an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid; and
(b) continuing the administration by orally administering, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

II

The defendants in this case are generic drug manufacturers who submitted Abbreviated New Drug Applications (“ANDAs”) to the FDA for approval to engage in the manufacture and sale of generic versions of Boniva prior to the expiration of Roche’s patents. Roche sued the defendants … alleging infringement under 35 U.S.C. § 271(e)(2) based on the defendants’ ANDA filings.

Roche moved for a preliminary injunction. The district court denied the motion, holding that Roche had failed to prove it was likely to succeed in defeating the defendants’ obviousness challenge. This court affirmed the district court’s denial of the preliminary injunction. See 496 Fed. Appx. 46 (Fed. Cir. 2012).

While the appeal of the preliminary injunction decision was pending, the district court granted the defendants’ motion for summary judgment of invalidity of claims 1-8 of the ’634 patent due to obviousness under 35 U.S.C. § 103(a). As to the frequency of dosing, the court found that once monthly oral dosing of ibandronate was established in the prior art. As to the amount of the monthly dose, the court found that the combination of several prior art references suggested a dosage level of about 150 mg per month, or at least indicated that a monthly dose of 150 mg was obvious to try.

The district court considered Roche’s evidence of objective considerations of nonobviousness but concluded that “Roche’s objective considerations evidence … is not sufficient to defeat the motion for summary judgment.” In response to Roche’s argument that the 150 mg once monthly dose gave results that were superior to a 2.5 mg daily dose, the court found that Roche had “pointed to no evidence in support of [its] claim that the skilled artisan would have been surprised that the 150 mg once-monthly dose was superior to the 2.5 mg daily dose.” The court refused to consider contentions, raised at oral argument, that the 150 mg dose had a superior and unexpected level of bioavailability, because Roche had not raised that argument in its opposition brief.

Pursuant to Federal Rule of Civil Procedure 56(f) the court then raised, on its own motion, the issue of summary judgment of invalidity of claims 1-10 of the ’957 patent. After considering the parties’ submissions, the court held those claims invalid for the same reasons that applied to the claims of the ’634 patent. Roche argued that it was unexpected that an intermittent ibandronate regimen would be effective in reducing fractures. But the court concluded that the evidence on which Roche relied failed to show that a person of skill in the art would not have had a reasonable expectation that the patented method would succeed in reducing fractures. The court explained that “empirical confirmation that a method for increasing bone mineral density helps increase bone strength enough that bones break less easily would not appear to be all that surprising.”
In its motion for reconsideration, Roche argued that the district court had improperly failed to consider evidence that the 150 mg dose of ibandronate showed an unexpected level of bioavailability as compared with lower doses. On the merits of that argument, the district court found that the “evidence that the 150mg dosage was absorbed better by the body simply has no relevance to the core finding that the difference between the 150mg dose and the prior art was small” and that there was a reasonable expectation of success with the 150 mg dose.

Roche timely appealed the grants of summary judgment of obviousness.

III

The issue in this case is whether it would have been obvious at the time of invention to select a once monthly oral dosing regimen of ibandronate to treat osteoporosis and to set that dose at 150 mg.

A. Monthly Dosing

1. A relatively infrequent dosing schedule has long been viewed as a potential solution to the problem of patient compliance stemming from the inconvenience of oral bisphosphonate regimens. Fosamax, a prior art bisphosphonate product sold by Merck & Co., was administered weekly, and several prior art references taught once monthly oral dosing of ibandronate or other bisphosphonates.

First, an article in the trade journal Lunar News entitled Update: Bisphosphonates (“Lunar News”) stated that “[r]esearchers are seeking solutions for better compliance,” including approaches that “use bisphosphonates with high potency yet low irritability, such as *** ibandronate (Roche). Oral agents could be given intermittently (once/month, for example) and still be quite potent.” Second, a 2001 article by Carey Krause in Chemical Market Reporter (“Krause”) disclosed that Roche would likely seek FDA approval of an “oral once-monthly” formulation of ibandronate in 2003. Finally, United States Patent No. 6,468,559 (“Chen”) disclosed coated-dosage forms of bisphosphonic acids and methods for orally administering those dosage forms. Ibandronic acid was identified as one of many known bisphosphonic acids. Chen disclosed a preferred embodiment in which “a dosage form of the invention is administered to a patient *** preferably once a month.” Lunar News, Krause, and Chen therefore specifically taught the monthly administration of ibandronate.

Similarly, the prior art contained references to the monthly oral administration of bisphosphonates in general. United States Patent Application No. 2003/0118634 (“Schofield”) taught dosing of “bone-active phosponate[s]” and referred to equivalent doses that “can be given every other day, twice a week, weekly, biweekly or monthly.” United States Patent No. 5,616,560 (“Geddes”) disclosed a bisphosphonate administration regimen in which “said bisphosphonate is administered at least 1 day of every said thirty(30)-day treatment period.”

2. Roche argues that the art taught away from once monthly dosing because, according to Roche, it was widely believed as of the date of invention that a bisphosphonate regimen with a dose-free interval longer than one or two weeks would not be effective. To support that contention, Roche primarily relies on the alleged failure of its intravenous ibandronate study (“Recker”) to demonstrate anti-
fracture efficacy with quarterly dosing. Secondarily, Roche relies on a prior art article by Thomas Schnitzer (“Schnitzer”) speculating that the failure of the Recker study was due to the long dose-free interval.

The Recker study, however, showed a 26% reduction in vertebral fractures with intravenous ibandronate administered once every three months. The study was a “failure” only in the sense that the 26% reduction was statistically insignificant given the large number of patients that would have been required to reach a statistically significant conclusion about the relative rates of fractures in the control and subject groups. With respect to the reduction of hip fractures, for example, Recker concluded that “a meaningful conclusion with regard to efficacy could not be made owing to the low absolute number of hip fractures.” Recker’s failure to generate statistically significant results points to a fault in the study; it does not teach that infrequent ibandronate dosing is ineffective in treating osteoporosis.

The prior art references that interpreted Recker’s results demonstrate only that it was unknown why Recker was unsuccessful in demonstrating statistically significant antifracture efficacy. Schnitzer speculated that the long drug-free interval was to blame for the inconclusive results and that dosing intervals longer than one or two weeks would be ineffective. On the other hand, an article by Dr. Dennis Black (“Black”) described speculation that the doses used in Recker were too low. In fact, Roche itself subsequently acknowledged that the Recker study was underdosed. Thus, Schnitzer’s speculation did not amount to an affirmative teaching away from monthly oral dosing of ibandronate, especially in the face of Black’s competing explanation of the Recker results.

Any doubt about the efficacy of oral ibandronate dosing that may have been created by Schnitzer’s speculation was put to rest by an article published in 2001 by Riis et al. entitled Ibandronate: A Comparison of Oral Daily Dosing Versus Intermittent Dosing in Postmenopausal Osteoporosis (“Riis”). Riis demonstrated that “intermittent ibandronate is as effective as the continuous treatment in terms of significantly increasing BMD at the spine and hip and suppressing markers of bone turnover.” Riis showed that increases in BMD equivalent to those obtained with a 2.5 mg per day treatment regimen were obtained with a regimen of 20 mg of ibandronate every other day for the first 24 days of every three-month period. Those results, Riis concluded, “confirm[ed] preclinical data showing that it is the total dose over a predefined period and not the dosing regimens that is the determining factor for effect on bone mass and architecture after ibandronate treatment.” Riis’s teaching that a dose-free interval of more than two months did not impact the BMD efficacy of ibandronate was directly contrary to Schnitzer’s speculation that such a dosing regimen would not be effective. Therefore, even if Schnitzer’s interpretation of the Recker study were viewed as teaching away from monthly dosing, Riis’s contrary findings substantially undermined that interpretation.

Roche argues that Riis did not overcome Schnitzer’s interpretation because Riis was not an antifracture trial. Roche argues that prior art focusing only on BMD and bone-turnover improvements, instead of on antifracture efficacy, does not bear on the obviousness analysis in this case because such prior art does not establish a reasonable expectation of success in reducing fracture risk.
While it is true that BMD improvements do not perfectly correlate with antifracture efficacy, it was well established in the art that BMD is a powerful surrogate for measuring fracture risk. For example, Roche’s own expert explained:

Bone mineral density is directly related to fracture risk. It is one of the most powerful surrogate markers in the field of medicine. It is as powerful an indicator of osteoporosis as blood pressure is a predictor of stroke. For every standard deviation reduction in bone mineral density, fracture risk is doubled.

Roche’s patents do not themselves present data demonstrating antifracture efficacy for a once monthly 150 mg dose. In fact, antifracture efficacy for Boniva was demonstrated to the FDA through a “bridging study” that used BMD and bone turnover results—not antifracture testing—to establish the therapeutic noninferiority of the 150 mg monthly dose relative to the previously approved 2.5 mg daily dose, for which antifracture efficacy had been demonstrated.

Conclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success. See PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1363-64 (Fed. Cir. 2007); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1364 (Fed. Cir. 2007). Riis—along with other prior art that used BMD improvement as the primary efficacy marker for treating osteoporosis—established at least a reasonable expectation that once monthly dosing of ibandronate could successfully treat osteoporosis and reduce fracture risk.

B. Selecting the 150 mg Dose

1. Riis confirmed the total-dose concept whereby “the efficacy of ibandronate depends on the total oral dose given rather than on the dosing schedule.” Riis therefore teaches that in setting the dosage level for an intermittent ibandronate regimen, one need only scale up a known-effective dose from a short-interval regimen—e.g., daily dosing—to achieve approximately the same BMD and bone-loss efficacy with a long-interval regimen.

The prior art provided substantial guidance as to the total dose, within a given time period, that would produce effective results. A 1996 article by Ravn et al. (“Ravn”) reported the results of a study that measured BMD improvements and bone-turnover markers for daily ibandronate doses of 0.25 mg, 0.5 mg, 1.0 mg, 2.5 mg, and 5 mg. The authors concluded that the “average change in bone mass showed positive outcome in all regions in the groups receiving ibandronate 2.5 and 5.0 mg.” The 2.5 mg dose exhibited a response that was “virtually equal” to the 5 mg dose, even though it contained only half the amount of ibandronate. The 2.5 mg dose was thereby deemed the “most effective dose.”

A person skilled in the art looking to scale to a monthly dose of oral ibandronate from a known-effective daily dose was thus faced with a very limited set of possibilities: Of the five daily doses tested in Ravn, only the 2.5 and 5 mg doses “showed positive outcome in all regions.” Even though the 5 mg dose did not demonstrate greater efficacy than the 2.5 mg dose, it was still deemed an equivalent-ly effective dose so that someone scaling it to a single monthly dose of 150 mg (5
mg/day x 30 days/month) would have anticipated equivalent success in raising BMD and limiting bone turnover, based on Riis.

Additionally, United States Patent No. 6,432,932 ("Daifotis") disclosed weekly doses of ibandronate “from the group consisting of 35 mg, 40 mg, 45 mg, or 50 mg.” The 35 mg weekly dose corresponds to the same total dose as a 5 mg daily dose. The total-dose equivalent to 5 mg of ibandronate per day is thus the only dose that appears in both Ravn and Daifotis—suggesting that there was a reasonable expectation of success with the total-dose equivalents of the 5 mg daily dose, i.e., 150 mg per month.

Accordingly, the prior art pointed to a monthly treatment of 150 mg of ibandronate. At the very least, the 150 mg dose was obvious to try: There was a need to solve the problem of patient compliance by looking to less-frequent dosing regimens. And, based on Ravn and Daifotis, in light of Riis’s total-dose concept, there were only a “finite number of identified, predictable solutions.” *KSR Int’l Co. v. Teleflex*, 550 U.S. 398, 421 (2007).

2. Roche contends that findings by the FDA taught away from further development of the 5 mg daily dose (and its total-dose equivalents) because the FDA approved a 2.5 mg daily dose of ibandronate instead of a 5 mg daily dose. But the FDA never made any findings contrary to the 5 mg daily dose, because it was never asked to approve that dose. Instead, in approving the 2.5 mg daily dose, the FDA merely restated the results of Ravn and concluded that “the 2.5 mg daily dose of ibandronate has the most favorable benefit–risk ratio and is the most appropriate dose for the prevention and treatment of postmenopausal osteoporosis.”

Roche next contends that Schofield taught away from using anything other than the lowest effective dose of a bisphosphonate, which, according to Roche, was established by Ravn to be 2.5 mg for ibandronate. Schofield, however, does not teach that the lowest effective dose is the only dose that should be used when treating osteoporosis with a bisphosphonate. Instead, Schofield merely defined the lowest effective dose as a measure of a drug’s potency relative to its therapeutic effects. Schofield then described a preferred embodiment of a method for treating bone disorders in which the maintenance dose of a “bone-active phosphonate” ranged from 2.5 to 15 mg per day. That range clearly encompasses more than just a lowest effective dose. Moreover, Ravn never purported to establish a lowest effective dose. Instead, it sought to establish a “most effective [daily] dose.”

Roche argues that the district court misinterpreted and misapplied the total-dose concept from Riis. According to Roche, the district court “took a technical leap” in finding that Riis’s total-dose concept implied only simple multiplication to scale from an efficacious daily dose to a monthly dose. The evidence before the district court, however, showed that the total-dose concept can be used as an effective rule of thumb by a person skilled in the art deciding how to scale to an efficacious intermittent dose of ibandronate. The Riis study, in particular, established that the total dose concept can reliably predict that the efficacy of an ibandronate treatment depends on the total dose administered to a patient over a given period, not on the amount administered at any single point in time. In light of that evidence, it was
reasonable to expect that a once monthly dose of 150 mg would have roughly the same efficacy as a daily dose of 5 mg.

C. Safety of the 150 mg Dose

Roche next contends that there are disputed issues of fact as to whether it would have been obvious to administer once monthly doses of 150 mg in light of alleged safety concerns about the adverse gastrointestinal effects of ibandronate and other bisphosphonates.

First, Roche argues that Ravn taught away from further development of the 5 mg daily dose, and thereby its total-dose equivalents, because Ravn taught that the 2.5 mg daily dose was more effective than the 5 mg daily dose and had fewer side effects. Ravn, however, concluded that “the responses in the groups receiving 2.5 and 5 mg ibandronate were virtually equal,” not that the 2.5 mg dose was more effective. And although patients on the 5 mg daily dose dropped out of the study at a higher rate than patients on lower doses, Ravn did not conclude that the higher drop-out rate was statistically significant. Instead, the authors merely noted that a higher frequency of diarrhea was experienced with the 5 mg dose. A higher frequency of diarrhea does not necessarily teach away from the 5 mg daily dose or its equivalents, however, as the prior art indicated that modest gastrointestinal side effects must be weighed in light of the benefits of the drug. Indeed, Ravn itself concluded that “[i]n the present study, the side effect profile of ibandronate seemed to be safe” and that “[i]n general, the safety evaluation did not reveal any differences between ibandronate and placebo treated groups.”

Moreover, even if the higher incidence of diarrhea and the larger number of dropouts in the Ravn study were initially enough to teach away from further development of the 5 mg daily dose and its total dose equivalents, any such teaching away would have been overcome by Riis’s finding that an oral administration of 20 mg of ibandronate every other day for 24 days, followed by a nine-week rest phase, resulted in the same rate of side effects as a 2.5 mg daily regimen.

Aside from Ravn, Roche does not point to any references suggesting that there were safety concerns associated with the 150 mg dose. Nor was Roche’s expert, Dr. Harris, aware of anything that taught that a once monthly, 150 mg dose of ibandronate would be unsafe.

To the contrary, the prior art establishes that doses even higher than 150 mg were considered safe. United States Patent No. 6,143,326 (“Möckel”) stated that rapid-release ibandronate formulations showed “no significant side effects *** in clinical studies using ibandronate even at high dosages” and disclosed single-dose units up to 250 mg. Defendants’ expert, Dr. Yates, testified that the disclosures in Möckel would have led a person of ordinary skill in the art to understand that ibandronate doses up to 250 mg would be well tolerated. Likewise, Daifotis disclosed that “[f]or human oral compositions comprising ibandronate *** a unit dosage typically comprises from about 3.5 mg to about 200 mg of the ibandronate compound.”

There is thus no genuine issue of fact concerning whether the prior art taught away from the 150 mg dose based on safety concerns.
D. Unexpected Results

Roche argues that the district court erred by granting summary judgment of obviousness because the evidence of record showed that the 150 mg monthly dose was more effective than the 2.5 mg daily dose and that the superior effectiveness of the 150 mg monthly dose was unexpected. Roche also contends that ibandronate’s nonlinear bioavailability at the 150 mg dosage level was an unexpected result.

Roche’s MOBILE study, published in 2005, demonstrated that a 150 mg monthly dose is more effective than a 2.5 mg daily dose with respect to BMD improvement in the lumbar spine and most hip sites. The MOBILE study demonstrated, for example, a mean BMD improvement in the lumbar spine of 4.9% after one year for patients taking the 150 mg monthly dose and 3.9% after one year for patients taking the 2.5 mg daily dose. Another study published in 2005 showed that the extent of ibandronate’s bioavailability is nonlinear with increasing dosages: Increasing the oral dose by 50 percent, from 100 mg to 150 mg, resulted in a nearly 150 percent increase in the amount of the drug absorbed by the blood.

While the evidence would support a finding of superior efficacy of the 150 mg monthly dose in raising BMD levels, as compared to a 2.5 mg daily dose, that improved efficacy does not rebut the strong showing that the prior art disclosed monthly dosing and that there was a reason to set that dose at 150 mg. See In re Merck & Co., 800 F.2d 1091, 1099 (Fed. Cir. 1986). The evidence of superior efficacy does nothing to undercut the showing that there was a reasonable expectation of success with the 150 mg monthly dose, even if the level of success may have turned out to be somewhat greater than would have been expected.

For the same reasons, the nonlinear bioavailability of ibandronate does not rebut the prima facie showing of obviousness of a once monthly dose of 150 mg. The increased level of bioavailability has not been shown to be responsible for the improved osteoporosis treatment efficacy of the 150 mg dose. A study by Ravn et al. in 2002 showed, for example, that a near doubling of the blood-serum concentration of ibandronate with a 5 mg daily dose, compared to a 2.5 mg daily dose, produced no further BMD increase and no further reduction in bone turnover. Other record evidence confirms that “[d]ue to strong binding to the bone surface, the effects of the systemically available amount of a bisphosphonate are almost exclusively related to its concentration in bone rather than [blood] serum level.” The evidence regarding bioavailability is therefore of little relevance to the obviousness inquiry.

Accordingly, we uphold the judgment of the district court that claims 1-8 of the ‘634 patent and claims 1-10 of the ‘957 patent would have been obvious in light of the prior art and are therefore invalid.
Common Sense & Objective Indicia

Plantronics, Inc. v. Aliph, Inc.

724 F.3d 1343 (Fed. Cir. 2013)

Wallach, Judge:

In this patent infringement case, Plantronics, Inc. ("Plantronics") filed suit alleging that Aliph, Inc. and Aliphcom, Inc.’s (collectively, “Aliph”) products infringe U.S. Patent No. 5,712,453, entitled “Concha Headset Stabilizer.” On March 23, 2012, the district court granted-in-part Aliph’s motion for summary judgment of noninfringement and invalidity, construing certain disputed terms, finding in relevant part that the accused products do not infringe claims 1 and 10, and holding the asserted claims invalid as obvious. The district court’s decision is reversed in part, vacated in part, and remanded for further proceedings.

Background

The ’453 patent is directed to a concha-style headset for transmitting received sounds to the ear of a user, e.g., headsets used with cell phone receivers. In particular, the patent discloses an apparatus for stabilizing a concha style headset during use. Because the claimed apparatus requires some familiarity with the human ear, an illustration is provided [at right.]

Of particular relevance is the concha, “a deep cavity containing the entry to the ear canal,” and which is divided into the upper and lower concha, 43 and 41.

Prior art headset stabilizers included large supports outside the ear or relied on appendages to hook onto the crux of the helix 31. The ’453 patent purports to improve upon prior art headset stabilizers. In particular, the claimed headset consists of “a receiver attachment that couples to the body of the receiver, a support member extending from the receiver attachment, and a concha stabilizer pad coupled to the end of the support member such that the concha stabilizer pad contacts the upper concha under the antihelix of the ear with the receiver placed in the lower concha in front of the ear canal.” Thus, the concha stabilizer pad has three points of contact: the tragus, the anti-tragus, and the upper concha. Certain embodiments of the claimed concha stabilizer are depicted below[.]

The stabilizing concha style headset is described as typically including a receiver 27 and a voice tube 30. A receiver attachment comprises an ear cushion 11 preferably dimensioned as an oblate spheroid, formed of a reticulated, fully open-pore flexible, ester type polyurethane foam. The ear cushion 11 has an open central recessed portion 13 forming a “C” shape, which is dimensioned to fit snugly onto the receiver 27. A flexible support member, stabilizer support 17, extends from the upper surface of the ear cushion 11. The end of the stabilizer support 17 is coupled to a concha stabilizer pad 21 which contacts the upper concha 43 beneath the anti-
The tragus contact point 23 and the antitragus contact point 25 with respect to the face 15 of the ear cushion 11 is reversed for the left and right ears.

Independent claim 1 is representative of the asserted claims:

1. An apparatus for stabilizing a headset including a receiver sized to fit between a tragus and an antitragus of an ear, the apparatus comprising:
   an ear cushion dimensioned to cover a portion of the receiver disposed between the tragus and the antitragus;
   a resilient and flexible stabilizer support member coupled to the ear cushion, and dimensioned to fit within an upper concha with the ear cushion coupled to the receiver and the receiver disposed between the tragus and the antitragus; and
   a concha stabilizer pad coupled to the stabilizer support member, for contacting the upper concha.

Independent claim 10 is also relevant here and is recited below:

10. A headset comprising:
   a receiver sized to fit between a tragus and an antitragus of an ear, the receiver having a tragus contact point, and an antitragus contact point disposed substantially opposite to the tragus contact point; an ear cushion dimensioned to cover a portion of the receiver; and
   a concha stabilizer coupled to the ear cushion and dimensioned to contact an upper concha between an antihelix and a crux of a helix with the receiver disposed between the tragus and the antitragus.

On January 15, 2009, Plantronics filed the underlying patent infringement suit against Aliph originally asserting claims 1, 7, 10 and 11. …

In its summary judgment decision, the district court … held claims 1, 7, 10, 11, 18, 20, 21, 26, 28, 30, 43 and 44 of the ’453 patent were invalid as obvious in light of the combination of U.S. Patent No. 1,893,474 (“Lieber”) with Japanese Utility Patent Application No. 60-40187(U) (“Komoda”). Furthermore, the district court determined that dependent claims 25, 29, 31-42 and 45-56 were obvious by the combination of the Lieber patent, the Komoda patent and U.S. Patent No. 5,048,090 (“Geers”). …
This court reviews a district court’s grant of summary judgment without deference. *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 704 (Fed. Cir. 2012). ... In addition, “a district court can properly grant, as a matter of law, a motion for summary judgment on patent invalidity when the factual inquiries into obviousness present no genuine issue of material facts.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991). “When the facts underlying an obviousness determination are not in dispute, we review whether summary judgment of invalidity is correct by applying the law to the undisputed facts.” *Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1366 (Fed. Cir. 2011).

Whether the claimed subject matter would have been obvious to an ordinarily skilled artisan at the time of the invention “is a question of law based on underlying questions of fact.” *Green Edge Enters., LLC v. Rubber Mulch Etc. LLC*, 620 F.3d 1287, 1298 (Fed. Cir. 2010). The underlying factual inquiries include: (1) “the scope and content of the prior art”; (2) “differences between the prior art and the claims at issue”; (3) “the level of ordinary skill in the pertinent art”; and (4) relevant objective considerations, including “commercial success, long felt but unsolved needs, [and] failure of others ***.” *KSR Int’l Co. v. Telesflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). Obviousness must be proved by clear and convincing evidence. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). The burden of proof lies with the challenger, and this court has rejected any formal burden-shifting framework in evaluating the four *Graham* factors. *OSRAM*, 701 F.3d at 709. Thus, the inquiry on summary judgment is whether a jury applying the clear and convincing evidence standard could reasonably find, based on the evidence produced by the accused infringer, that the claimed invention was obvious. *See TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1339-40 (Fed. Cir. 2010).

The gravamen of the parties’ dispute here involved whether a skilled artisan would have been motivated to combine certain prior art references, an issue that focuses heavily on the first and third *Graham* factors. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) (“[T]he motivation to combine requirement entails consideration of both the scope and content of the prior art and level of ordinary skill in the pertinent art aspects of the *Graham* test.”). The district court found that Lieber and Komoda disclosed “a receiver, ear cushion, stabilizer support and pad” and that any gap between these prior art elements and those recited, in relevant part, claims 1 and 11 of the ’453 patent was bridged by “common sense.” In particular, the district court determined that (1) the need for a stabilizing member that worked with the anatomy of an ear was a problem known in the art at the time of the invention, (2) there was a trend towards miniaturization of in-the-ear devices, and (3) miniaturizing the receiver described in Lieber and Komoda while pairing the receiver with a comfortable, adaptable, and stabilizing ear cushion as claimed in the ’453 patent was a matter of common sense for those skilled in the art at the time of the invention.
“An invention may be a combination of old elements disclosed in multiple prior art references.” Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1321 (Fed. Cir. 2005). Applying a flexible approach to the obviousness inquiry, the Supreme Court observed that common sense can be a source of reasons to combine or modify prior art references to achieve the patented invention. KSR, 550 U.S. at 420. Therefore, motivation to combine may be found explicitly or implicitly in market forces; design incentives; the “interrelated teachings of multiple patents”; “any need or problem known in the field of endeavor at the time of invention and addressed by the patent”; and the background knowledge, creativity, and common sense of the person of ordinary skill. Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1328-29 (Fed. Cir. 2009) (quoting KSR, 550 U.S. at 418-21).

Although the obviousness analysis is somewhat flexible, a district court’s conclusions with respect to obviousness must find support in the record. In determining that a person of skill in the art would have been motivated to combine the references at issue, the district court did not cite any expert testimony indicating that there was a motivation to combine. Instead, the court determined that common sense would motivate a skilled artisan to combine the relevant references’ teachings. As we have said before though:

“the mere recitation of the words ‘common sense’ without any support adds nothing to the obviousness equation.” Mintz v. Dietz & Watson, 679 F.3d 1372, 1377 (Fed. Cir. 2012). Thus, we have required that [obviousness findings] grounded in “common sense” must contain explicit and clear reasoning providing some rational underpinning why common sense compels a finding of obviousness. See KSR, 550 U.S. at 418; In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

In re Nouvel, 493 Fed. Appx. 85, 92 (Fed. Cir. 2012). Where, as here, the necessary reasoning is absent, we cannot simply assume that “an ordinary artisan would be awakened to modify prior art in such a way as to lead to an obviousness rejection.” Id. It is in such circumstances, moreover, that it is especially important to guard against the dangers of hindsight bias.

As a safeguard against “slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue,” we have required courts to consider evidence of the objective indicia of nonobviousness prior to making the ultimate determination of whether an invention is obvious. Graham, 383 U.S. at 36; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983) (objective considerations “may often be the most probative and cogent evidence [of nonobviousness] in the record”). Failure to give proper consideration to such evidence, as in this case, can be fatal because “common sense” may not be so apparent in view of objective evidence of nonobviousness (e.g., commercial success and copying), particularly when all reasonable inferences are drawn in favor of the patentee. See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors
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USA, Inc., 617 F.3d 1296, 1305 (Fed. Cir. 2010) (reversing for failure to consider the objective evidence of nonobviousness and because there are genuine issues of material fact remaining as to objective considerations).

Here, the district court concluded that the ’453 patent was invalid as obvious before considering objective indicia of nonobviousness. According to the district court, “[i]t would have been obvious to one of ordinary skill in the art to modify the Lieber device to reduce the size of the in-the-ear receiver while pairing the receiver with a comfortable, adaptable ear cushion that stabilized the device with a flexible support member that invoked the ear anatomy to avoid the use of headsets and ear-hooks.” The district court addressed Plantronics’ objective evidence of nonobviousness—including copying and commercial success—only after reaching this conclusion. It stated: “Even accepting as true Plantronics’ assertions on these secondary considerations, they do not save Plantronics from summary judgment here since such secondary considerations simply cannot overcome a strong prima facie case of obviousness.” To the extent the district court conducted a post hoc analysis of objective considerations, it was improper.

This court has consistently pronounced that all evidence pertaining to the objective indicia of nonobviousness must be considered before reaching an obviousness conclusion. See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1076 (Fed. Cir. 2012). The significance of this fourth Graham factor cannot be overlooked or be relegated to “secondary status.” See id. at 1079. …

Plantronics contends that it presented evidence of copying and commercial success that at least raise genuine issues of material fact underlying the ultimate conclusion of obviousness. For example, Plantronics argues that the design of Aliph’s accused product began with Plantronics’ concha-style headset stabilizer, that it is undisputed that Aliph initially installed Plantronics’ stabilizer into Aliph’s headset, and from there, that Aliph copied Plantronics’ design. Plantronics also avers that it presented evidence that the functional fit provided by the copied design is critical to Aliph’s headset, establishing a nexus between the secondary evidence and the claimed invention. With the copied design, Plantronics argues that Aliph enjoyed commercial success. In response, Aliph contends that the evidence Plantronics presented was not sufficient, but otherwise does little to rebut the evidence. The district court’s scant consideration of relevant objective evidence belies Aliph’s argument.

The full extent of the district court’s analysis was as follows: “In support of these secondary considerations, Plantronics relies, in part, upon the supplemental report of its expert, Barry Katz. Consistent with the evidentiary rulings above, I did not rely on this supplemental, unsworn expert report.” The district court also stated: “I did not find Plantronics’ evidence of secondary considerations, to the extent it was not in expert reports I did not consider, particularly persuasive. For example, I found nothing helpful in the Drysdale testimony ***.” These statements, alone, fail to provide any meaningful analysis for this court’s review. Nevertheless, Aliph asks that we reject Plantronics’ objective considerations by finding in the first instance that Plantronics’ evidence is not tied adequately to the full scope of the asserted claims. This argument is without merit because “[i]t is not our role to scour the
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record and search for something to justify a lower court’s conclusions, particularly at the summary judgment stage.” OSRAM, 701 F.3d at 707. “[T]his court must be furnished sufficient findings and reasoning to permit meaningful appellate scrutiny.” Id. The district court’s opinion lacked such findings and reasoning.

Moreover, we cannot discern whether the district court, in this summary judgment context, drew all justifiable inferences in favor of Plantronics and found no disputed issues of material fact to support its holding with respect to obviousness. Transocean, 617 F.3d at 1305 (stressing that a court must draw all reasonable inferences in favor of a patent owner with respect to objective evidence of nonobviousness in the context of a motion for summary judgment of obviousness). In fact, when all of the factual disputes regarding the objective evidence are resolved in favor of Plantronics, we cannot hold that the claims would have been obvious as a matter of law. See id. (“Viewing the objective evidence of nonobviousness in a light most favorable to Transocean, we cannot hold that the claims would have been obvious as a matter of law.”); see also Simmons Fastener Corp. v. Ill. Tool Works, Inc., 739 F.2d 1573, 1576 (Fed. Cir. 1984) (reversing the lower court, in part, because evidence of objective considerations, particularly commercial success, was extremely strong and entitled to great weight). The commercial success of Aliph’s alleged copied product and the failure of attempts to combine the prior art elements before the ’453 patent provide a genuine issue of material fact as to whether it would be “common sense” to combine the elements in the prior art to arrive at the claimed invention. Because evidence pertaining to objective considerations raises genuine issues of material fact, the district court’s decision is reversed as to all the asserted claims in this case.3

Randall Mfg. v. Rea
733 F.3d 1355 (Fed. Cir. 2013)

Taranto, Judge:

FG Products owns U.S. Patent No. 7,214,017, which is directed to moveable bulkheads for partitioning cargo space in a shipping container. FG’s competitor, Randall Manufacturing, requested inter partes reexamination of the ’017 patent, and the ... examiner rejected a number of FG’s claims as obvious over a combination of four prior-art references. On appeal, the Board ... reversed, unable to discern any reason that one of ordinary skill in the art would have been motivated to combine the cited references. Randall appeals the Board’s determination to this court. Because the Board failed to consider a wealth of well-documented knowledge that is highly material to evaluating the motivation to combine references to arrive at the claimed invention, we vacate the Board’s decision and remand the matter.

3 The district court also erred to the extent it invalidated the unasserted claims of the ’453 patent or to the extent the district court invalidated claims not at issue in the motion before it. Accordingly, to the extent the district court’s final judgment invalidates patent claims not at issue, that determination is vacated.

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Background

FG and Randall are competitors in selling products for refrigerated trucks. In particular, both parties manufacture moveable, track-mounted bulkheads (partitions) used for dividing cargo space. The ’017 patent, issued on May 8, 2007, discloses partitioning apparatuses that include two half-width panels independently mounted on the ceiling of a shipping container using rail-and-trolley assemblies, so that the panels may be strapped together to form a full-width partition, separately moved along the length of the container for separate positioning, or raised and stowed against the ceiling. Figures 1, 6, and 7 are illustrative[.]

On December 4, 2007, Randall requested inter partes reexamination of the ’017 patent. The Examiner granted Randall’s request and subsequently rejected all 15 original claims of the ’017 patent. In response, FG amended or canceled its original claims and added 78 new claims. Three years of additional prosecution ensued, including consideration of dozens of prior-art references, resulting in a series of rejections, responses, and amendments. New claim 38 is representative of FG’s claims on appeal:

An apparatus for separating cargo areas in a trailer, comprising:

a trailer that includes a cargo space;

first and second panels, each panel extending in a direction generally perpendicular to a longitudinal axis of the trailer, wherein when in a first operative position the first and second panels are arranged in a side-by-side configuration and abut one another along adjacent peripheral edges of the panels;

fastening straps that releasably secure the first and second panels together in the side-by-side configuration to form a full-width bulkhead that extends between opposing sidewalls of the cargo space of the trailer;

a mounting system that provides each of the first and second panels with a first degree of freedom to convey the panels in a longitudinal direction independently of one another and that provides each of the first and second panels with a second degree of freedom to raise the panels independently, … and

a first lift mechanism mounted proximate to a longitudinal end of at least one of the first set of two longitudinal rails … and

a second lift mechanism mounted proximate to a longitudinal end of at least one of the second set of two longitudinal rails ….

Ultimately, the Examiner allowed many of FG’s new and amended claims, but rejected [many other] claims … as obvious over a combination of four references:
two advertisements from third-party bulkhead manufacturer ROM; U.S. Patent No. 3,217,664, issued to Aquino; and U.S. Patent No. 1,193,254, issued to Gibbs. The Examiner cited the ROM references for their disclosure of half-width panels with straps for positioning and joining the panels together to form a full-width partition, as depicted below:

The Examiner cited Aquino for its disclosure of independently movable half-width panels mounted on the ceiling of a container using rail-and-trolley assemblies:
The Examiner cited Gibbs for its disclosure of a panel that can be lifted by means of a lift mechanism and stowed near the ceiling of a container:

The Examiner concluded that all of the elements of the rejected claims were well known at the time of FG’s application and that it would have been obvious to one of ordinary skill in the art to combine them.

FG appealed the Examiner’s obviousness rejections to the Board, arguing that one of ordinary skill in the art would not have been motivated to combine the cited references, both because of alleged physical impediments to their combination and because the references each taught distinct features that were at cross-purposes with one another. In particular, FG argued that the lift mechanism of Gibbs would be incompatible with Aquino, that the panels of Aquino could not be lifted to the ceiling of the container without colliding with the rails on which they were mounted, and that Aquino, in providing for stowage of its panels against the wall of the container, taught away from ceiling stowage. FG supported its contentions with declarations from named inventor and FG co-owner Chad Nelson.

In its briefing before the Board, Randall argued that the state of the art and the level of skill at the time of FG’s application included well-known options for lifting moveable, track-mounted bulkheads and stowing them against the ceiling. As evidence of what one of ordinary skill in the art would have known, Randall cited a host of references that had been considered by the Examiner during the course of the reexamination—some of which had provided the basis for rejecting FG’s original claims—including multiple references disclosing track-and trailer-mounted bulkheads that could be raised to the ceiling, and a variety of references teaching straps and lift mechanisms to assist in stowage. Randall also provided a declaration from its employee, Gregory Boyer, who confirmed that a bulkhead designer at the time of FG’s application would have recognized that the panels of Aquino could be raised and stowed near the ceiling, noting references showing that it was well known how to adjust the geometry of a track-mounted assembly so that the rails would not interfere with lifting the panel.

At oral argument before the Board, patentee FG stated that “we concede that raising of doors is known” and that the “crux” of its appeal focused specifically on Aquino and “why one would modify Aquino when Aquino already provides a solu-
tion for stowing the door.” Randall, in contrast, stressed the broad range of knowledge demonstrated in the art “going back close to a hundred years,” arguing that “a person of ordinary skill in the art would think of this because raising panels to the ceiling, at this point in time, was so pervasive.” Randall contended that the side stowage of panels shown in Aquino was the exception rather than the rule, and that “raising them to the ceiling was the standard method of getting a panel out of the way.”

In its decision reversing the Examiner on the rejections at issue here, the Board did not consider the background references Randall had cited as evidence of the knowledge of one of skill in the art. Instead, the Board looked to “the content of the prior art relied upon in rejecting FG Products’ claim 1.” Analyzing just Aquino, Gibbs, and the two ROM references, and focusing specifically on modifying Aquino to allow ceiling stowage, the Board found that it “simply does not follow” that ceiling stowage “would have been contemplated for Aquino’s assembly for which there is no need or intent for such a position.” The Board observed that “the nature and extent of the raising of the panels” was “at the center of the dispute,” but unable to identify any reason that one of skill in the art would have sought to modify Aquino to include ceiling stowage, the Board reversed the Examiner’s obviousness rejections … .

Discussion

…

In KSR, the Supreme Court criticized a rigid approach to determining obviousness based on the disclosures of individual prior-art references, with little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications. KSR, 550 U.S. 398, 415-22 (2007). Rejecting a blinkered focus on individual documents, the Court required an analysis that reads the prior art in context, taking account of “demands known to the design community,” “the background knowledge possessed by a person having ordinary skill in the art,” and “the inferences and creative steps that a person of ordinary skill in the art would employ.” Id. at 418. This “expansive and flexible approach,” id. at 415, is consistent with our own pre-KSR decisions acknowledging that the inquiry “not only permits, but requires, consideration of common knowledge and common sense.” DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367 (Fed. Cir. 2006).

The Board’s analysis in this case ran afoul of that basic mandate. By narrowly focusing on the four prior-art references cited by the Examiner and ignoring the additional record evidence Randall cited to demonstrate the knowledge and perspective of one of ordinary skill in the art, the Board failed to account for critical background information that could easily explain why an ordinarily skilled artisan would have been motivated to combine or modify the cited references to arrive at the claimed inventions. As KSR established, the knowledge of such an artisan is part of the store of public knowledge that must be consulted when considering whether a claimed invention would have been obvious.
In recognizing the role of common knowledge and common sense, we have emphasized the importance of a factual foundation to support a party’s claim about what one of ordinary skill in the relevant art would have known. See, e.g., Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1377 (Fed. Cir. 2012); Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1328 (Fed. Cir. 2009). One form of evidence to provide such a foundation, perhaps the most reliable because not litigation-generated, is documentary evidence consisting of prior art in the area. Randall relied on just such evidence in citing to extensive references of record showing a familiar, even favored, approach to bulkhead stowage. For instance, Randall cited four U.S. patents (Nos. 1,148,382; 2,752,864; 2,866,419; and 4,019,442) that disclose bulkheads designed to be lifted and stowed near the ceiling, three of which (the ’382, ’864, and ’419 patents) describe such stowage for movable, track-mounted panels. The significance of those and other references did not depend on any attempt to change the combination that formed the basis of the Examiner’s rejections; rather, the references constitute important evidence of the state of the art and the context in which the Examiner-cited combination should be evaluated.

The Board’s failure to consider that evidence—its failure to consider the knowledge of one of skill in the art appropriately—was plainly prejudicial.\(^3\) Once it is established that a prevalent, perhaps even predominant, method of stowing a bulkhead panel was to raise it to the ceiling, it is hard to see why one of skill in the art would not have thought to modify Aquino to include this feature—doing so would allow the designer to achieve the other advantages of the Aquino assembly while using a stowage strategy that was very familiar in the industry.\(^4\) Moreover, although FG claims that, as depicted, the panels of Aquino may have been impeded by the rails from being raised all the way to the ceiling, there is no dispute that it would have been well within the capabilities of an ordinary bulkhead designer to adjust the geometry (e.g., drop the hinge axis down a few inches) so that the panels could be freely raised to the ceiling. There are no apparent functional concerns that would have discouraged a bulkhead designer of ordinary skill from attempting the combination.

Particularly when viewed in the context of the background references Randall provided, the evidence strongly supports the notion that the bulkhead design FG claimed was nothing more than the “combination of familiar elements according to known methods,” “each performing the same function it had been known to perform,” “yield[ing] predictable results.” KSR, 550 U.S. at 416-17 (quoting Sakrai-

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\(^3\) Although the Examiner did not articulate this analysis, Randall, as the appellee before the Board, was entitled to defend the Examiner’s rejection on this ground, which it had presented in the record. Rexnord Indus., LLC v. Kappos, 705 F.3d 1347, 1355-56 (Fed. Cir. 2013).

\(^4\) Familiarity may be reason enough, but the widespread industry use of ceiling stowage may reflect particular judgments. At least in some situations, for instance, it may be more important to reserve space for cargo at the sides of a container than near the ceiling, as packing cargo against the walls helps distribute weight more evenly and may be easier than piling cargo toward the ceiling.
In re Chaganti
554 Fed. Appx. 917 (Fed. Cir. 2014)

Per Curiam

Naren Chaganti appeals from the decision of the Board affirming the obviousness rejections of all the claims of U.S. Patent Application No. 09/634,725. Because the factual findings underlying the Board’s conclusion are supported by substantial evidence, and because the Board did not commit legal error, we affirm.

Background

The invention claimed in Mr. Chaganti’s ’725 application is a method and system for providing limited access to articles, books, music, movies, and other copyrighted content through the Internet pursuant to a license. The system examines copyright license information to ensure that persons requesting access to the content have such access only for a particular amount of time or during particular time periods. The invention also allows for a limited number of requestors to simultaneously access information. Finally, the invention uses a formatting program that enables content to be viewed on the requestor’s device. Claims 45 through 61 are at issue in this appeal. Claim 45 is representative:

A server-computer implemented method of providing online repository services to a plurality of users *** comprising ***:

establishing on the server computer connected to the Internet an account for each of a plurality of users;

storing on the server computer a copyright-protected information object;

and

controlling access to the copyright-protected information object by one or more of the plurality of users in accord with one or more restrictions.

Illustrative claims that depend from claim 45 add the further limitations of: “examining license information for the copyright-protected information object to determine a number N (where N ≥ 1) of simultaneous users who could access the copyright-protected information object” (claim 48); allowing access to the copyrighted information “for a predetermined time” and during a particular “time period” (claim 49 and 50); and “formatting” the copyrighted information so that it is “suitable to the requirements of a user’s device” (claim 51). The examiner rejected the pending claims as unpatentable over U.S. Patent No. 7,243,079 (Manolis) in view of U.S. Patent No. 6,453,305 (Glassman).

Manolis discloses a system that enables users to purchase prints of their digital photographs online and share photographs online. Manolis discloses that a “user optionally can share his/her online photos (i.e., those images that the user has up-
loaded to the host computer system) with other users *** .” Sharing photos online “causes the host system to set access permissions as appropriate to allow the intended share recipient to access the online images specified by the user.” Manolis also discloses creating and displaying an image thumbnail for each of the uploaded photographs.

Glassman discloses an “electronic commerce system and method [that] enforces a license agreement for content on an open network by restricting the number of consumers that can concurrently access the content.” It discloses tracking “the users of [a] web site and block[ing] users who are not licensed or who have exceeded the scope of the applicable license.” Glassman also describes an embodiment in which a vendor of copyrighted content has a license that permits a fixed number of users to access content at any given time. This embodiment further allows the vendor to “check[] to determine whether there is an available license (i.e., whether an additional consumer is allowed to view the content under the license).” Glassman also discloses that the length of time and the time period during which customers are given access to copyrighted content may be controlled.

Discussion

A. Analogous Art

The parties dispute whether Manolis is analogous art. “Two separate tests define the scope of analogous prior art: (1) whether the art is from the same endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004). The Board found that Manolis is analogous to the claimed invention under the first test, concluding that “both the invention and Manolis’ teachings are directed to systems which allow for the storage and retrieval of information objects by a plurality of users.” Mr. Chaganti argues that there is no substantial evidence that Manolis is analogous art. He contends that Manolis is not concerned with copyright-protected information and “the Board did not explain why it ignored this key differentiator” in finding that Manolis was relevant.

We agree with the PTO that Manolis is analogous art. Because both Manolis and the claimed invention are directed to the controlled distribution of content via the Internet, they have essentially the same function and are in the same field of endeavor. The fact that Manolis does not specify that the photographs distributed by the system are copyrighted does not suggest that a skilled artisan would not consult Manolis. Manolis need not disclose every limitation of the claimed invention to fall within the same field of endeavor as the claimed invention.

B. Teaching Away

In finding that the claims of the ’725 application would have been obvious in view of the combination of Manolis with Glassman, the Board found that Glassman does not teach away from the claimed invention. Mr. Chaganti argues that the Board’s finding lacks substantial evidence. He contends that Glassman’s statement
that “existing lock servers are undesirable on an open network” teaches away from using existing lock server architectures to provide controlled access to copyrighted material on an open network.

While Glassman describes the then-existing lock servers as “undesirable,” we disagree that this constitutes a teaching away from mechanisms for controlling Internet access to copyrighted material. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994). Glassman delineates the “undesirable” features of existing lock servers, but it also lists various features that a lock server should incorporate to avoid those deficiencies. Glassman affirmatively states that the “method and system for electronic commerce” disclosed meets those needs. Glassman further teaches the use of a locking mechanism to police content use over the Internet and states that it is an object of the invention to “allow enforcement of an N-user license for content located on an open network like the Internet.” Therefore, we find that substantial evidence supports the Board’s conclusion that Glassman does not teach away from the claimed invention’s disclosure of limiting Internet access to copyrighted material.

C. Reason to Combine

The Board found that a person of skill in the art would have had reason to combine Manolis with Glassman to arrive at the claimed invention. Mr. Chaganti argues that the Board erred by failing to articulate that reason. He contends that the Board’s reason to combine the references was motivated by hindsight bias. He further argues that the Board erred by failing to make factual findings with respect to the level of ordinary skill in the field of the invention.

We disagree. The Board found that a person of ordinary skill would have had a reason to use “the online print service of Manolis to provide licensed access to copyrighted images in order to provide account users with the ability [to] control access to their copyrighted images” while “at the same time providing concurrent access to the images as suggested by Glassman.” We read this as a statement that common sense would have provided a reason to combine these references. We find this persuasive given that, while Manolis does not specify that the images distributed by the system are copyrighted, they almost certainly are. See 17 U.S.C. § 102. Common sense would have provided a person of ordinary skill with reason to use the teachings of Glassman to distribute these copyrighted images under the appropriate licenses. Substantial evidence supports the Board’s finding.

Nonetheless, Mr. Chaganti’s argument regarding the lack of a stated reason to combine is not unreasonable. We caution the Board and the PTO that such reasons must be clearly articulated. It is not enough to say [as the Board did] that there would have been a reason to combine two references because to do so would “have been obvious to one of ordinary skill.” Such circular reasoning is not sufficient—more is needed to sustain an obviousness rejection.

We agree with the PTO that the absence of factual findings with respect to the level of ordinary skill in the field of the invention does not “give rise to reversible
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error” where, as here, “the prior art itself reflects an appropriate level and a need for testimony is not shown.” Okajima v. Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Moreover, Mr. Chaganti has not made any showing that a finding regarding the level of ordinary skill would impact the ultimate conclusion of obviousness under § 103. See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 963 (Fed. Cir. 1986).

D. Dependent Claims

The Board found that Glassman teaches examining a license to determine a number N of authorized concurrent users (claim 48), as well as restricting the amount of time or time periods during which the requestor is given access to the information (claims 49 and 50). With respect to claims 51 and 57-60, the Board affirmed the examiner’s finding that Manolis’ description of creating thumbnail images of photographs teaches “formatting” information and using a formatter as required by those claims.

Mr. Chaganti disputes the Board’s findings. First, he argues that Glassman does not examine license information to determine N, as required by claim 48, but instead starts with a known N. Next, he contends that Glassman does not disclose the step of receiving licensing information indicating that the license is for access of information for a predetermined time (T_license) as required by claim 49. Similarly, he contends that Glassman does not disclose the step of determining a time period (T) during which the copyright-protected information object may be accessed as required by dependent claim 50.

With respect to dependent claims 51, and 57-60, Mr. Chaganti seems to argue that the Board misconstrued the terms “formatting,” “formatter,” and “format.” However, Mr. Chaganti does not offer any construction of these terms. Instead, he argues only that the creation of thumbnail images from a photograph as disclosed in Manolis does not constitute formatting an image in a manner suitable to a user’s device. He contends that the thumbnails Manolis discloses are created at the time of uploading an image and before a user is allowed access to online photographs and thus are not formatted to be “suitable to the requirements of a user’s device.”

We agree with the PTO that substantial evidence supports the Board’s findings that the combination of Manolis and Glassman discloses each limitation of dependent claims 48-50, 51, and 57-60, and renders these claims obvious. First, with respect to dependent claim 48, there is substantial evidence that Glassman teaches using license information to determine the number of users, N, that are allowed to access content, and does not arbitrarily predetermine this number. For instance, Glassman describes an embodiment in which “[p]referably, the vendor *** maintains a data structure associated with the licensed content that can be quickly scanned to determine whether a license is available.” In this embodiment, the vendor “checks to determine whether there is an available license”—suggesting that the number of users is determined on the basis of what the license allows. Next, with respect to dependent claims 49 and 50, there is substantial evidence that Glassman discloses limiting access to copyrighted information “for a predetermined time” and during a fixed “time period.” Glassman discloses that “permission to access specific content *** may be unlimited or it may be for only a relatively brief period of time,
say a few minutes to a few hours.” It further teaches that “optionally, [the invention] provides the consumer with an estimate of when a license will be available.”

Finally, we also agree with the PTO that substantial evidence supports the Board’s finding that Manolis discloses formatting content and using a formatting program as required by dependent claims 51 and 57-60. Manolis describes formatting uploaded photographs to display them as thumbnail images on a user’s device.

We have considered Mr. Chaganti’s remaining arguments and find them unpersuasive. Because each of the pending claims would have been obvious in light of the combination of Manolis and Glassman, we do not reach the Board’s additional bases for rejecting the claims.

…
Chapter 7: Infringement

Mueller’s Patent Law: 439-442 (top of page), 466-489

The Doctrine of Equivalents

Mueller’s Patent Law: 489-499

Brilliant Instruments Inc. v. GuideTech, LLC
707 F.3d 1342 (Fed. Cir. 2013)

Moore, Judge:

GuideTech, LLC (GuideTech) appeals from the district court’s grant of summary judgment that Brilliant Instruments, Inc. (Brilliant) did not infringe three related GuideTech patents: U.S. Patent Nos. 6,226,231; 6,091,671; and 6,181,649. Because the court erred in granting summary judgment, we reverse and remand.

Background

This appeal arises from a declaratory judgment action that Brilliant filed after the inventor of the patents-in-suit left GuideTech to found Brilliant. GuideTech’s patents generally relate to circuits that measure the timing errors of digital signals in high-speed microprocessors. These circuits, which are referred to as time interval analyzers, detect timing errors by analyzing a digital circuit’s clock signal and output signals.

The patents share a common specification and claim different aspects of the time interval measuring circuit. The ’231 patent claims the circuit at a high level, reciting that the circuit comprises a “signal channel,” a “plurality of measurement circuits defined within said signal channel,” and a “processor circuit.” Claim 1 is representative of the claims at issue:

A time interval analyzer for measuring time intervals between signal events, said analyzer comprising:

a signal channel that receives an input signal;

a plurality of measurement circuits defined within said signal channel in parallel with each other; and

a processor circuit in communication with said signal channel.

(Emphasis added). The issue on appeal with regard to the ’231 patent is whether Brilliant’s time interval analyzers have “a plurality of measurement circuits defined within said signal channel.” For purposes of this appeal, the parties agree that Brilliant’s accused BI200 and BI220 products operate identically. Both products employ a “One-Channel-Two-Edge” mode in which they operate using “a single channel” and use two measurement circuits.

The ’671 and ’649 patent claims are directed to internal circuitry of a measurement circuit. Claim 1 of the ’671 patent is representative:

A time interval analyzer for measuring time intervals between events in an input signal, said analyzer comprising:
*** a first current circuit having a constant current source or a constant current sink ***;
a second current circuit ***;
a capacitor; [and] a shunt, wherein said shunt and said capacitor are operatively disposed in parallel with respect to said first current circuit, wherein said shunt is disposed between said first current circuit and said second current circuit ***.

(Emphasis added). The issue on appeal regarding the '671 and '649 patents is whether the measurement circuits in the BI200 and BI220 contain a capacitor “operatively disposed in parallel” with respect to a first current circuit. In its infringement allegations, GuideTech identified a capacitor that is part of the alleged “first current circuit.”

The district court construed the disputed claim terms and entered summary judgment of noninfringement in favor of Brilliant for all three patents. GuideTech appeals. …

Discussion

... Infringement, either literal or under the doctrine of equivalents, is a question of fact. Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009). “Thus, on appeal from a grant of summary judgment of noninfringement, we must determine whether, after resolving reasonable factual inferences in favor of the patentee, the district court correctly concluded that no reasonable jury could find infringement.” Id. (quoting IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1429 (Fed. Cir. 2000)).

II. Infringement of the ’231 Patent

GuideTech challenges the district court’s grant of summary judgment of noninfringement of the ’231 patent. At summary judgment, the court construed the “defined within said signal channel” limitation as “contained within a signal channel.” It further defined a “signal channel” as “an electrical circuit that includes a signal path for transmitting electrical signals.” Neither party challenges these constructions.

The district court concluded that GuideTech failed to present sufficient evidence that the BI200 and BI220 have multiple measurement circuits contained within a signal channel. The court held that, although the accused products require the use of two measurement circuits, “it does not follow that both circuits are contained in a single channel.” The court concluded that the testimony of GuideTech’s expert, Dr. West, failed to show that the measurement circuits were “contained” in the same channel.

GuideTech argues that the district court erred in concluding that there was no genuine issue of material fact. GuideTech points to Dr. West’s expert report, arguing that it shows that the BI200 and BI220 employ two circuits contained within a single channel when operating in the One-Channel-Two-Edge mode. GuideTech
also argues that Brilliant’s datasheets show that the accused products operate on a single channel and use two measurement circuits.

Brilliant argues that the district court properly granted summary judgment. Brilliant argues that it cannot infringe because the district court, as a matter of claim construction, rejected GuideTech’s argument that “defined within” allowed a measurement circuit to be present in more than one channel. Brilliant argues that the B1200 and B1220 do not infringe because each signal channel contains only one measurement circuit and simply borrows a second measurement circuit during One-Channel-Two-Edge mode.

We agree with GuideTech that the district court erred when it granted summary judgment. A genuine issue of material fact exists as to whether the B1200 and B1220, when operating in One-Channel-Two-Edge mode, have two measurement circuits contained within a signal channel, i.e., an electrical circuit that includes a signal path for transmitting electrical signals. Dr. West explained how the B1200 and B1220 meet the asserted claims when operating in One-Channel-Two-Edge mode. Brilliant’s schematics also show that, during operation in One-Channel-Two-Edge mode, the only active signal path flows from the input to two measurement circuits:

In the above schematic, a user sets the circuit to One-Channel-Two Edge Mode with Channel A as the input. The signal path during operation in this mode is highlighted in the above schematic. Once received, the signal first flows through a comparator. The signal then flows into two multiplexers. The outputs of the multiplexers are then input into two measurement circuits (the timetag circuits).

This schematic and Dr. West’s testimony, viewed in GuideTech’s favor, shows that the only signal channel operative during One-Channel-Two-Edge mode contains two measurement circuits. This evidence raises a genuine issue of material fact as to whether Brilliant’s products literally infringe the ’231 patent claims. Accordingly, the district court erred when it granted Brilliant’s motion for summary judgment, and we reverse and remand for further proceedings.

III. Infringement of the ’671 and ’649 Patents

GuideTech also challenges the district court’s grant of summary judgment that Brilliant’s accused products do not infringe the ’671 and ’649 patents. The district
court construed the term “operatively disposed in parallel” to mean “arranged in a manner capable of forming alternative paths of current such that current can flow across one or the other path.” The parties do not challenge that construction on appeal.

The district court concluded that Brilliant was entitled to summary judgment because Dr. West conceded that the capacitor in Brilliant’s products is “part of the first current circuit.” The court concluded that Dr. West’s testimony indicated “that the capacitor is not on an alternative path on which current flows from the first current circuit.” Because it was undisputed that the capacitor in the accused products was part of the first current circuit and not arranged in parallel with the first current circuit, the court concluded that the accused products do not infringe the ’671 and ’649 patents, either literally or under the doctrine of equivalents.

GuideTech argues that nothing in the claims precludes the capacitor from being part of the first current circuit and, at the same time, operatively disposed in parallel with the shunt. It points to Dr. West’s expert report, arguing that he opined that the measurement capacitor and the shunt are arranged to form alternate current paths during operation. Finally, GuideTech argues that Dr. West explained how the operation of the accused products was equivalent to operatively disposing the shunt and capacitor in parallel with respect to the first current circuit.

Brilliant responds that its products cannot literally infringe because it was undisputed that the accused capacitor is part of the first current circuit, not disposed in parallel with respect to it. Brilliant argues that GuideTech’s infringement theory under the doctrine of equivalents fails because it would vitiate the requirement that the claimed “first current circuit” and the “capacitor” are separate elements.

We agree with Brilliant that the district court properly granted summary judgment that Brilliant’s accused products do not literally infringe. The claims recite “said shunt and said capacitor are operatively disposed in parallel with respect to said first current circuit.” It is undisputed that in Brilliant’s accused product the capacitor is part of the first current circuit. Because, according to the undisputed facts, GuideTech cannot establish literal infringement, summary judgment of no literal infringement was appropriately granted.

We agree with GuideTech, however, that the district court erred when it granted summary judgment that Brilliant does not infringe under the doctrine of equivalents. To find infringement under the doctrine of equivalents, any differences between the claimed invention and the accused product must be insubstantial. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). One way of proving infringement under the doctrine of equivalents is to show, for each claim limitation, that the accused product “performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.” *Crown Packaging*, 559 F.3d at 1312. This is a question of fact. Id.; *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1313 (Fed. Cir. 2003).

In this case, GuideTech submitted an expert report by Dr. West that detailed its doctrine of equivalents theory under the function-way-result test. Brilliant does not contest Dr. West’s recitations of the function, way, and result of the asserted claims.
or the accused products. Nor does Brilliant provide any contrary evidence. Instead, it argues that GuideTech’s doctrine of equivalents infringement theory vitiates the requirement that the claimed “first current circuit” and the “capacitor” are separate claim elements.

Brilliant’s vitiation argument fails. As we recently explained in *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349 (Fed. Cir. 2012):

“Vitiation” is not an exception to the doctrine of equivalents, but instead a legal determination that “the evidence is such that no reasonable jury could determine two elements to be equivalent.” The proper inquiry for the court is to apply the doctrine of equivalents, asking whether an asserted equivalent represents an “insubstantial difference” from the claimed element, or “whether the substitute element matches the function, way, and result of the claimed element.” If no reasonable jury could find equivalence, then the court must grant summary judgment of no infringement under the doctrine of equivalents.

*Id.* at 1356. The vitiation concept has its clearest application “where the accused device contain[s] the antithesis of the claimed structure.” *Planet Bingo, LLC v. GameTech Int’l, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006). This makes sense; two elements likely are not insubstantially different when they are polar opposites. As we explained in *Deere*, “[c]ourts should be cautious not to shortcut this inquiry by identifying a ‘binary’ choice in which an element is either present or ‘not present.’ Stated otherwise, the vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure or process because the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute.” *Deere*, 703 F.3d at 1356-57. The vitiation test cannot be satisfied merely by noting that the equivalent substitute is outside the claimed limitation’s literal scope. Rather, vitiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result. In short, saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device based on the well-established “function-way-result” or “insubstantial differences” tests.

To succeed on a doctrine of equivalents theory, the patentee must demonstrate equivalence under one of these two tests. This will be more difficult when the accused structure has an element that is the opposite of the claimed element, especially where the specification or prosecution history highlights the differences. If the claimed and accused elements are recognized by those of skill in the art to be opposing ways of doing something, they are likely not insubstantially different. The concept of vitiation is an acknowledgement that each element in the claim must be present in the accused device either literally or equivalently. And we have applied this concept to cases where we have recognized that two alternatives exist that are very different from each other and therefore cannot be equivalents for infringement purposes. See, e.g., *Planet Bingo*, 472 F.3d at 1345 (concluding that determining a winning combination after a game starts was not equivalent to determining a winning
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combination before the game starts); Moore U.S.A., Inc. v. Std. Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000) (“[I]t would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise.”).

Applying these concepts to the facts of this case, we conclude that summary judgment must be reversed. The element at issue is: “wherein said shunt and said capacitor are operatively disposed in parallel with respect to said first current circuit.” Dr. West, GuideTech’s expert, agreed that in the accused device, the measurement capacitor is a component of the first current circuit. While this disposers of literal infringement, the doctrine of equivalents inquiry is: did GuideTech create a genuine issue of material fact regarding whether Brilliant’s capacitor, located within the first current circuit, performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed capacitor, which is operatively disposed in parallel to the shunt? Everyone agrees that the capacitor in the accused device is not located in exactly the same place as the claimed capacitor, but is the change in location an insubstantial difference? We conclude that, viewing all factual inferences in favor of GuideTech, it has created a genuine issue of material fact which precludes summary judgment. Dr. West explained:

The electrical disposition of the shunt and the capacitor with respect to the first current circuit of the BI200 and BI220 is equivalent to the electrical disposition of the shunt and the capacitor with respect to the first current circuit of this claim limitation because it performs substantially the same function (allowing the shunt to control the path of current flow to or from the first current circuit) in substantially the same way (wherein an electrical path from the first current circuit can be traced to either the capacitor or the shunt) to achieve substantially the same result (providing an electrical relationship wherein, e.g., the shunt can direct current to flow from the first current circuit to the second current circuit or from the first current circuit to the capacitor).

This detailed application of the function-way-result test to the claim element and the allegedly equivalent feature of the accused product is sufficient to create a genuine issue of material fact for the jury to resolve. The main difference between the accused circuit and the claimed circuit is that the capacitor in the accused circuit aids in delivering power and is thus part of the first current circuit. There is, however, no evidence suggesting that this added advantage of the accused design alters Dr. West’s function-way-result analysis. On this record, GuideTech has created a genuine issue of material fact which precludes summary judgment of noninfringement under the doctrine of equivalents.

Dyk, Judge, concurring in part & dissenting in part:

I agree with the majority with respect to the ’231 patent, and with its holding that there is no literal infringement of the ’671 patent and ’649 patent. However, I disagree with the majority that a genuine issue of material fact remains as to infringement of the ’671 and ’649 patents under the doctrine of equivalents.
The only relevant claim limitation at issue with respect to the '671 and '649 patents requires that the “shunt and *** capacitor [be] operatively disposed in parallel with respect to [the] first current circuit.” The district court construed the “operatively disposed in parallel” portion of this limitation to mean “arranged in a manner capable of forming alternative paths of current such that current can flow across one or the other path.” It also implicitly recognized, however, that the remaining portion of this limitation required that this current flow be “with respect to” the first current circuit.

There is no dispute in this case that the capacitor in the accused device was part of the first current circuit and therefore inside of that circuit. Thus, the capacitor could not possibly be disposed in parallel “with respect to” something of which it is already a part. The district court, in rendering a judgment of noninfringement for Brilliant, therefore emphasized that “the capacitor is not on an alternative path on which current flows from the first current circuit.” (Emphasis added). The majority acknowledges that “in Brilliant’s accused product the capacitor is part of the first current circuit,” and holds that “GuideTech cannot establish literal infringement” of either the '671 or the '649 patent. However, the majority rejects the district court’s conclusion that this fact “preclude[d] a finding of infringement *** under the doctrine of equivalents.” In so doing, it relied on GuideTech’s expert report from Dr. West as raising a genuine issue of material fact.

I disagree. The function-way-result test for equivalents requires “showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result.” Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009) (emphasis added). Similarly, we have recently reiterated that “[r]egardless [of] how the equivalence test is articulated, ‘the doctrine of equivalents must be applied to individual limitations of the claim, not to the invention as a whole.’” Mirror Worlds, LLC v. Apple Inc., 692 F.3d 1351, 1357 (Fed. Cir. 2012) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997)) (emphasis added). This guidance to consider each claim limitation under the doctrine of equivalents flows from the principles of claim vitiation, which require a determination of whether there is a substantial difference or a difference in kind between each individual claim limitation and the accused product. See Trading Techs. Int’l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1355 (Fed. Cir. 2010).

While Dr. West purports to follow this guidance, in fact Dr. West’s report is inconsistent with the approach articulated in the cases. It applies the equivalent to the invention as a whole rather than to the particular claim limitation at issue. The Dr. West expert report, in reciting the function-way-result of the claimed invention, states:

[T]he electrical disposition of the shunt and the capacitor with respect to the first current circuit of the BI200 and BI220 is equivalent to the electrical disposition of the shunt and the capacitor with respect to the first current circuit of this claim limitation because it performs substantially the same function (allowing the shunt to control the path of current flowing to or from the first current circuit) in substantially the same way (wherein an elec-
trical path from the first current circuit can be traced to either the capacitor or the shunt) to achieve substantially the same result (providing an electrical relationship wherein, e.g., the shunt can direct current to flow from the first current circuit to the second current circuit or from the first current circuit to the capacitor).

(Emphasis added). As the majority properly asks, “[e]veryone agrees that the capacitor in the accused device is not located [such that it is operatively disposed in parallel with respect to the first current circuit], but is the change in location an insubstantial difference?” Dr. West’s report fails to even address this question.

The “same result” Dr. West contends is achieved by the accused device is a result where “the shunt can direct current to flow from the first current circuit to the second current circuit or from the first current circuit to the capacitor.” (Emphasis added). But this “same result” cannot occur in the accused device, as it is undisputed that, because the capacitor is inside the first current circuit, current cannot flow from the first current circuit to the capacitor. An appropriate doctrine of equivalents analysis would have identified an identical result that was achieved in both the claimed invention and the accused invention, thereby demonstrating that the difference between the two was insubstantial. But there is no evidence in the record—from Dr. West or elsewhere—explaining why the difference between the claimed invention and the accused device (i.e., that the capacitor in the accused device is located inside, as opposed to outside, the first current circuit) is insubstantial or how the function-way-result test is satisfied as to this limitation.

Once Brilliant brought forth expert evidence that its devices were outside the scope of the claim limitations under a doctrine of equivalents analysis, the burden fell on “the nonmoving party [in this case, Guidetech] to set forth specific facts showing that there is a genuine dispute for trial.” Minkin v. Gibbons, P.C., 680 F.3d 1341, 1349 (Fed. Cir. 2012); Shum v. Intel Corp., 633 F.3d 1067, 1076 (Fed. Cir. 2010). This Guidetech did not do. Indeed, given that no evidence exists showing that Brilliant’s accused products met the “with respect to” portion of the relevant limitation under the doctrine of equivalents, Brilliant merely needed to point out, as it did, “that there is an absence of evidence to support [Guidetech’s infringement] case.” Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

Accordingly, I respectfully dissent as to this aspect of the majority’s opinion, and I would affirm the district court’s judgment of noninfringement as to the ’671 and ’649 patents under the doctrine of equivalents.

Ring & Pinion Serv. Inc. v. ARB Corp.

743 F.3d 831 (Fed. Cir. 2014)

Moore, Judge:

Defendant ARB Corporation Ltd. (ARB) appeals from the district court’s grant of summary judgment of noninfringement of U.S. Patent No. 5,591,098 (the ’098 patent) to Ring & Pinion Service, Inc. (R&P). Because the district court erred by improperly applying the doctrine of claim vitiation, we reverse and remand with instructions to enter judgment of infringement for ARB.
Background

The invention claimed in the '098 patent is an improved automobile locking differential. A differential is a mechanism that allows wheels to rotate at different speeds relative to each other. When locked, a locking differential distributes torque from the engine such that both wheels spin at the same rate. Claim 1 is representative:

A locking differential comprising
a differential carrier *** ,
a locking means *** ,
cylinder means formed in said differential carrier and housing an actuator position[ed] to cause movement of said locking means relative to said carrier
(Emphasis added).

R&P sought declaratory judgment that its Ziplocker product did not infringe the '098 patent. Following claim construction, the parties cross-moved for summary judgment. After briefing was complete, the parties jointly stipulated that there were “no issues of material fact regarding infringement under the doctrine of equivalents.” The parties agreed that the Ziplocker product literally met every limitation of claim 1 except the “cylinder means formed in” limitation, but that the Ziplocker included an “equivalent” cylinder. Moreover, the parties agreed that the cylinder in the Ziplocker “would have been foreseeable to a person having ordinary skill in the art at the time the application for the '098 patent was filed.”

The parties agreed that “should the Court hold *** that foreseeability of an equivalent at the time of application prevents use of the doctrine of equivalents, *** the accused differential would not infringe under the doctrine of equivalents.” In the alternative, they further agreed that “should the Court hold *** that foreseeability at the time of application does not prevent use of the doctrine of equivalents, *** the accused differential would infringe under the doctrine of equivalents.” Thus, the parties agreed that the outcome of the case would be determined by the resolution of a single legal issue: whether an equivalent is barred under the doctrine of equivalents because it was foreseeable at the time of the patent application. The district court entered an order approving the parties’ joint stipulation. Subsequently, the court requested that the parties submit additional briefing to address the all-limitations rule.

The court held that, while foreseeability did not preclude the application of the doctrine of equivalents, a finding of infringement under the doctrine of equivalents would vitiate the “cylinder means formed in *** ” limitation. Therefore, the court granted summary judgment of non-infringement to R&P. ARB appeals. …

Discussion

…

I

In ruling on the parties’ summary judgment motions, the district court held that “foreseeability at the time of [patent] drafting alone[,] is not a formally recog-
nized limitation on the doctrine of equivalents.” R&P argues that the district court erred. Relying principally on *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997), R&P contends that we have found that the doctrine of equivalents does not apply to equivalents that were foreseeable at the time of the patent application. It argues in the alternative that the doctrine of equivalents has been found to exclude foreseeable equivalents under certain circumstances and that we should extend those exclusions to create a per se foreseeability bar to application of the doctrine.

We do not agree. There is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents. It has long been clear that known interchangeability weighs in favor of finding infringement under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 36 (1997) (“The known interchangeability of substitutes for an element of a patent is one of the express objective factors * * * bearing upon whether the accused device is substantially the same as the patented invention.”); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950) (holding that “whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was” is an “important factor” weighing in favor of equivalence); *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1382 (Fed. Cir. 2006) (finding that “known interchangeability” is a “factor to consider in a doctrine of equivalents analysis” that “aids the fact-finder in assessing the similarities and differences between a claimed and an accused element.”); *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1383 (Fed. Cir. 2001) (holding that “the known interchangeability test looks to the knowledge of a skilled artisan to see whether that artisan would contemplate the interchange as a design choice.”); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1261 (Fed. Cir. 1989) (finding that “the substitution of an ingredient known to be an equivalent to that required by the claim presents a classic example for a finding of infringement under the doctrine of equivalents.”). Excluding equivalents that were foreseeable at the time of patenting would directly conflict with these holdings that “known interchangeability” supports infringement under the doctrine of equivalents. We conclude that the foreseeability of an equivalent at the time of patenting is not a bar to a finding of infringement under the doctrine of equivalents.

R&P’s reliance on *Sage Products* to argue that a general foreseeability bar to the doctrine of equivalents exists is misplaced. *Sage Products* held that claim vitiation, not foreseeability, prevented the application of the doctrine of equivalents in that case because its application “would have utterly written” express limitations “out of the claim.” *Overhead Door Corp. v. Chamberlain Grp., Inc.*, 194 F.3d 1261, 1271 (Fed. Cir. 1999) (citing 126 F.3d at 1423-25). “[B]ecause the scope of the claim” in *Sage Products* “was limited in a way that plainly and necessarily excluded a structural feature that was the opposite of the one recited in the claim, that different structure could not be brought within the scope of patent protection through the doctrine of equivalents.” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346 (Fed. Cir. 2001) (citing 126 F.3d at 1425). *Sage Products* did
not create a foreseeability limitation on the doctrine of equivalents, but instead held that a finding of infringement under the doctrine of equivalents would vitiate a claim limitation based on the facts of that case.

Relying on our holding in Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc., 145 F.3d 1303 (Fed. Cir. 1998), R&P argues that there is a foreseeability bar to the application of the doctrine of equivalents for means-plus-function limitations. R&P misstates the law. There is no such foreseeability limit on the doctrine of equivalents, nor did we create one in Chiuminatta.

In Chiuminatta, we explained that there are two differences between the equivalence determination made for literal infringement purposes under § 112(f) and a doctrine of equivalents determination for the same limitation: timing and function. 145 F.3d at 1310. Equivalence under § 112(f) is evaluated at the time of issuance. Al-Site Corp. v. VSI Int’l, Inc., 174 F.3d 1308, 1320 (Fed. Cir. 1999). Equivalence under the doctrine of equivalents, in contrast, is evaluated at the time of infringement. Id. Hence, an after-arising technology, a technology that did not exist at the time of patenting, can be found to be an equivalent under the doctrine of equivalents even though it cannot be an equivalent under the literal infringement analysis of § 112(f). Id.

The second difference between literal infringement and doctrine of equivalents infringement under § 112(f) relates to the function of the element. For literal infringement, the accused structures must perform the function recited in the claim (identical function). The doctrine of equivalents covers accused structures that perform substantially the same function in substantially the same way with substantially the same results. The doctrine of equivalents thus covers structures with equivalent, but not identical, functions. This is true whether the accused equivalent was known at the time of patenting or later arising. As we explained in Interactive Pictures, whether the accused structure “predates” the patent or is after-arising technology, the doctrine of equivalents applied to a means-plus-function clause requires only that equivalent structures perform substantially the same function. 274 F.3d at 1381-82. Where a finding of non-infringement under § 112(f) is based solely on the lack of identical function, it does not preclude a finding of equivalence under the doctrine of equivalents. Id. at 1382.

As we have explained in other cases, when the accused technology was known at the time of patenting and the functions are identical, the structural equivalence inquiry under § 112 and the structural equivalence portion of the doctrine of equivalents are coextensive. Al-Site Corp., 174 F.3d at 1320 n.2 (holding that for pre-existing structures where the functions are identical “any analysis for equivalent structure under the doctrine of equivalents collapses into the [§ 112(f)] analysis.”) (emphasis added); see also Welker Bearing Co. v. PHD, Inc., 550 F.3d 1090, 1100 (Fed. Cir. 2008); Frank’s Casing Crew & Rental Tools, Inc. v. Weatherford Int’l, Inc., 389 F.3d 1370, 1379 (Fed. Cir. 2004). Nothing in Chiuminatta or in any other case cited by R&P supports its assertion that there exists a foreseeability exception to the doctrine of equivalents that applies to means-plus-function or any other claim terms.
We agree with the district court that foreseeability does not create a bar to the application of the doctrine of equivalents. Given the joint stipulation, this conclusion should have resolved the case and the court should have entered a judgment of infringement pursuant to the stipulation.

II

In its order, the district court concluded that finding that the accused cylinder design was equivalent to the recited “cylinder means formed in ***” limitation would vitiate the claim limitation as a matter of law, and thus granted R&P’s motion for summary judgment of noninfringement. The court did not discuss the impact of the joint stipulation on its summary judgment ruling.

ARB argues that, once the district court determined that foreseeability does not prevent the application of the doctrine of equivalents, it should have enforced the parties’ joint stipulation by entering the stipulated finding of infringement. It contends that the district court reviewed and entered the joint stipulation and that R&P is bound by it.

We … agree with ARB that the district court erred by failing to enforce the parties’ stipulation. A stipulation of fact that is fairly entered into is controlling on the parties and the court is generally bound to enforce it. See Am. Title Ins. Co. v. Lace-law Corp., 861 F.2d 224, 226 (9th Cir. 1988). Here, the parties stipulated to equivalence, which is a question of fact, and agreed that there were no remaining issues of fact. See Deere & Co. v. Bush Hog, LLC, 703 F.3d 1349, 1356 (Fed. Cir. 2012). The district court nonetheless held that a finding of infringement under the doctrine of equivalents would vitiate the “cylinder means formed in ***” limitation. That was legal error.

Vitiation is “not an exception to the doctrine of equivalents, but instead a legal determination that the evidence is such that no reasonable jury could determine two elements to be equivalent.” Deere, 703 F.3d at 1356; see Brilliant Instruments, Inc. v. GuideTech, LLC, 707 F.3d 1342, 1347 (Fed. Cir. 2013). The parties’ stipulation precludes the conclusion that the “cylinder means formed in ***” limitation is vitiated because it states that the Ziplocker includes an equivalent to that limitation. Thus, we hold that the court erred by failing to grant summary judgment of infringement to ARB under the doctrine of equivalents.

…
Joint Infringement & Active Inducement

Muniauction, Inc. v. Thomson Corp.

532 F.3d 1318 (Fed. Cir. 2008)

Gajarsa, Judge:

This is a patent infringement case. Thomson Corporation and I-Deal, LLC (collectively “Thomson”) appeal from a final judgment, after a jury trial, that the asserted claims of U.S. Patent No. 6,161,099 are not obvious, that Thomson willfully infringed the asserted claims of the ’099 patent, that Muniauction, Inc. is entitled to approximately $77 million for lost profits damages enhanced for Thomson’s willful infringement, and that Thomson is permanently enjoined from continued infringement of the ’099 patent. Because claims 1, 9, 14, 31, 36, and 56 of the ’099 patent are obvious as a matter of law, the judgment of nonobviousness is reversed as to these claims. Similarly, because Thomson does not infringe the remaining asserted claims as a matter of law, the judgment of infringement is reversed, and the remainder of the final judgment is vacated.

Background

The ’099 patent is directed to electronic methods for conducting “original issuer auctions of financial instruments.” Col. 2, ll. 49-50. Specifically, the ’099 patent is directed to original issuer municipal bond auctions over an electronic network, e.g., the Internet, using a web browser. In this type of auction, the municipality (“issuer”) offers its bonds to underwriters (“bidders”), who typically bid on and purchase the entire bond offering, i.e., all-or-none bidding, and thereafter resell individual bonds to the public. A bond offering may be a package of debt instruments consisting of bonds having different principle amounts and having different maturity dates. A bidder submits a price and a related interest rate represented by a coupon for each of the bonds differentiated by a respective maturity date. ... In addition to all-or-none bidding, the ’099 patent discloses maturity-by-maturity bidding by which a bidder may bid on less than the entire debt offering.

The ’099 patent discusses many prior art electronic auction and trading systems, yet criticizes those systems as inapplicable to original issuer auctions of financial instruments. The ’099 patent also discusses the Parity electronic bid submission system, developed by 21st Century Municipal, Inc. for use in municipal bond auctions. “The PARITY bid submission system allows bidders who have previously obtained and installed appropriate software to electronically submit bids in an auction over a computer network.” Col. 3, ll. 4-7. The ’099 patent criticizes the Parity system for three reasons. First, the prior art system requires bidders to obtain and install the Parity software prior to participating in an auction over the computer network; second, the system “is designed to be used together with fax and other bid submission methods during an auction”; and third, the system operates as a sealed bid system in which the received bids are not evaluated and no feedback is provided to the bidders until the auction closes.
Accordingly, the invention of the '099 patent provides an “integrated system on a single server” that allows issuers to run the auction and bidders to prepare and submit bids using a conventional web browser, without the use of other separate software. Col. 5, ll. 13-28. The system of the '099 patent also allows issuers to monitor the progress of the auction and allows bidders to monitor their bid vis-à-vis the current best bid. Claim 1 states:

In an electronic auction system including an issuer’s computer having a display and at least one bidder’s computer having an input device and a display, said bidder’s computer being located remotely from said issuer’s computer, said computers being coupled to at least one electronic network for communicating data messages between said computers, an electronic auctioning process for auctioning fixed income financial instruments comprising:

inputting data associated with at least one bid for at least one fixed income financial instrument into said bidder’s computer via said input device;

automatically computing at least one interest cost value based at least in part on said inputted data, said automatically computed interest cost value specifying a rate representing borrowing cost associated with said at least one fixed income financial instrument;

submitting said bid by transmitting at least some of said inputted data from said bidder’s computer over said at least one electronic network; and

communicating at least one message associated with said submitted bid to said issuer’s computer over said at least one electronic network and displaying, on said issuer’s computer display, information associated with said bid including said computed interest cost value,

wherein at least one of the inputting step, the automatically computing step, the submitting step, the communicating step and the displaying step is performed using a web browser.

The accused process has as its genesis the Parity system discussed in the '099 patent. ... In 1997, Thomson acquired Parity from 21st Century Municipals and integrated [its preexisting] BidComp [product with] Parity ... into a single system marketed as BidComp/Parity. In 1998, Thomson modified BidComp/Parity to allow issuers to view bids over the Internet using a web browser rather than over a proprietary computer network.

On June 1, 2001, Muniauction filed suit against Thomson ... .

Discussion

...
pute that no single party performs every step of the asserted claims. For example, at least the inputting step of claim 1 is completed by the bidder, whereas at least a majority of the remaining steps are performed by the auctioneer’s system (e.g., Thomson’s BidComp/Parity system). The issue is thus whether the actions of at least the bidder and the auctioneer may be combined under the law so as to give rise to a finding of direct infringement by the auctioneer.

In *BMC Resources*, this court clarified the proper standard for whether a method claim is directly infringed by the combined actions of multiple parties. The court’s analysis was founded on the proposition that direct infringement requires a single party to perform every step of a claimed method. 498 F.3d at 1380 (concluding that this requirement derived directly from 35 U.S.C. § 271(a)); see also *NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005) (holding that users of accused system could not infringe method claims in the United States because one step of the method was performed in Canada). Yet the court recognized a tension between this proposition and the well-settled rule that “a defendant cannot thus avoid liability for direct infringement by having someone else carry out one or more of the claimed steps on its behalf.” *Id.* at 1379. Accordingly, where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises “control or direction” over the entire process such that every step is attributable to the controlling party, i.e., the “mastermind.” *Id.* at 1380-81. At the other end of this multi-party spectrum, mere “arms-length cooperation” will not give rise to direct infringement by any party. *Id.* at 1371.

Under *BMC Resources* then, the issue of infringement in this case turns on whether Thomson sufficiently controls or directs other parties (e.g., the bidder) such that Thomson itself can be said to have performed every step of the asserted claims. ... The jury instruction on joint infringement [used in this case] read as follows:

Consider whether the parties are acting jointly or together in relation to the electronic auction process. Are they aware of each other’s existence and interacting with each other in relation to the electronic auction process? Is there one party teaching, instructing, or facilitating the other party’s participation in the electronic auction process? These are the types of questions that you should ask in making your decision on this issue. If you find that there is a sufficient connection between Thomson and the bidders and the issuers that used Thomson’s process, then you could find Thomson liable for direct infringement.

However, ... none of the questions identified by the jury instruction are relevant to whether Thomson satisfies the “control or direction” standard of *BMC Resources*. That Thomson controls access to its system and instructs bidders on its use is not sufficient to incur liability for direct infringement.

Under *BMC Resources*, the control or direction standard is satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method. 498 F.3d at 1379; accord *Int’l Rectifier v. Samsung Elecs. Co.*, 361 F.3d 1355, 1361 (Fed. Cir. 2004) (reversing district court’s ruling that Sam-
sung violated a permanent injunction prohibiting infringement in the United States on the grounds that Samsung did not control or participate in the extraterritorial activities of a third party such that the acts of the third party were not attributable to Samsung). In this case, Thomson neither performed every step of the claimed methods nor had another party perform steps on its behalf, and Muniauction has identified no legal theory under which Thomson might be vicariously liable for the actions of the bidders. Therefore, Thomson does not infringe the asserted claims as a matter of law.

...
sales representative that supports that attach the luminaires to the ring had fallen off due to severe weather conditions. Zeller returned to Wyoming that month to fix the supports. After Zeller lowered the assembly, he concluded that the iris arms worked properly even after the Wyoming winter and despite the luminaire-to-ring support failure. On his way back to Ohio, Zeller stopped in Cheyenne and sought state approval for purchase of the iris arm device as fulfilling the original contract. In April 1972, Wyoming officials inspected the device and authorized payment. The rest area was opened to the public in June 1972.

Meanwhile, on February 7, 1972, Zeller had begun pursuing an iris arm design for two-foot diameter poles. Manville subsequently delayed shipments of lowering devices so that the new iris arms could be included. On March 10, 1972, Manville approved the iris arms for commercial use. Manville began notifying its sales staff of the decision to use the iris arms on March 15, 1972, and the iris arms first appeared in Manville’s owners’ manuals one week later. On April 20, 1972, Manville installed an iris arm in Nebraska. A patent application was filed on February 5, 1973, that later issued as the ‘333 patent.

In 1984, Anthony DiSimone, Paramount’s corporate secretary, obtained a copy of a drawing of Manville’s iris arm device that had been submitted to the Florida Department of Transportation. DiSimone sent the drawing to Robert Butterworth, Paramount’s president. Butterworth gave the drawing to Ralph Bloom, a Paramount designer, for use in designing a self-centering raise/lower device that was later made and sold by Paramount.

Manville filed suit against Paramount on July 14, 1986, alleging infringement of the ‘333 patent. DiSimone and Butterworth were added as party-defendants on March 11, 1987. After a bench trial, the district court found direct infringement by Paramount, pursuant to 35 U.S.C. § 271(a), and direct and induced infringement by DiSimone and Butterworth, pursuant to 35 U.S.C. § 271(a) & (b). …

…

Analysis

III. Personal Liability of Paramount’s Officers

A. Direct Infringement – 35 U.S.C. § 271(a)

Section 271(a) provides that “whoever without authority makes, uses or sells any patented invention **infringes the patent.” For Butterworth and DiSimone, officers of Paramount, to be personally liable for Paramount’s infringement under § 271(a), there must be evidence to justify piercing the corporate veil. See A. Strucki Co. v. Worthington Indus., Inc., 849 F.2d 593, 596 (Fed. Cir. 1988). Often a party asking a court to disregard the corporate existence will attempt to show that the corporation was merely the alter ego of its officers. See Zubik v. Zubik, 384 F.2d 267, 271-72 (3d Cir. 1967). More generally, a court may exert its equitable powers and disregard the corporate entity if it decides that piercing the veil will prevent fraud, illegality, injustice, a contravention of public policy, or prevent the corporation from shielding someone from criminal liability. Id. at 272. The court, however, must “start from the general rule that the corporate entity should be recognized and
upheld, unless specific, unusual circumstances call for an exception.” Id. at 273. Moreover, unless there is at least “specific intent to escape liability for a specific tort *** the cause of justice does not require disregarding the corporate entity.” Id.

In the instant case, the district court determined that Butterworth and DiSimone were personally liable for direct infringement. The district court based this decision on its finding that Butterworth and DiSimone took actions that assisted the copying of Manville’s design. DiSimone obtained a drawing of Manville’s iris arm design from the Florida Department of Transportation. He sent it to Butterworth who passed it on to Paramount’s designer for use in designing Paramount’s self-centering device. Although these facts support the conclusion that the officers had knowledge of their acts, these acts were within the scope of their employment and thus were protected by the corporate veil. See W. Fletcher, 10 Fletcher Cyclopedia of the Law of Private Corporations § 4877 at 323-24 (rev. perm. ed. 1986).

Nonetheless, the court held them personally liable. The court did so despite having concluded that Paramount was not the alter ego of the officers. Moreover, the court had found that the “evidence at trial did not demonstrate that Paramount knew of Manville’s patent prior to this lawsuit” and that Paramount’s subsequent infringing activity continued because of Paramount’s good faith belief, based on the advice of counsel, that it was not infringing. Although the district court made these findings explicitly with respect to Paramount, we conclude that these findings must also apply to Butterworth and DiSimone; any contrary knowledge or belief by the officers would have been imputed to the corporation under agency principles. See 3 Fletcher Cyclopedia § 832 at 171.

Based on the district court’s own underlying findings, and the record presented to us, we conclude that the court’s determination that Butterworth and DiSimone were personally liable, because it was based on piercing the corporate veil, was an abuse of its equitable powers. The district court’s findings establish that the officers were acting within the scope of their employment. The court’s findings preclude any inference that Butterworth and DiSimone were attempting to avoid liability under the protection of the corporate veil. Accordingly, we reverse as to the liability of the officers in their individual capacities with respect to infringement under § 271(a).

B. Active Inducement to Infringe – 35 U.S.C. § 271(b)

Section 271(b) provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” Under this section, corporate officers who actively assist with their corporation’s infringement may be personally liable for inducing infringement regardless of whether the circumstances are such that a court should disregard the corporate entity and pierce the corporate veil. See Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1578-79 (Fed. Cir. 1986). The alleged infringer must be shown, however, to have knowingly induced infringement. Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988). It must be established that the defendant possessed specific intent to encourage another’s infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have
known his actions would induce actual infringements. See id.; see also Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468-69 (Fed. Cir. 1990).

In the instant case, the district court determined, pursuant to § 271(b), that Butterworth and DiSimone were liable for inducing infringement. The court did so, however, after finding that like Paramount, Butterworth and DiSimone were not aware of Manville’s patent until suit was filed and that Paramount’s subsequent infringing acts continued upon Butterworth’s and DiSimone’s “good faith belief,” based on advice of counsel, that Paramount’s product did not infringe.

Based on the district court’s own findings and the record presented to us, we conclude that the district court’s decision to hold Butterworth and DiSimone liable under § 271(b) was contrary to law. There is simply neither compelling evidence nor any findings that the officers had specific intent to cause another to infringe. We therefore reverse as to the liability of the officers in their individual capacities with respect to infringement under § 271(b).

...  

**DSU Medical Corp. v. JMS Co.**

471 F.3d 1293 (Fed. Cir. 2006) *(en banc* in part)

Rader, Judge:

DSU Medical Corporation (DSU) and Medisystems Corporation (MDS) (collectively DSU) sued JMS Company, Limited (JMS) and JMS North America (collectively JMS) and ITL Corporation Pty, Limited (ITL) for patent infringement, inducement to infringe, and contributory infringement of United States Patent Nos. 5,112,311 and 5,266,072. ...

I.

The ’311 and ’072 patents claim a guarded, winged-needle assembly. The invention reduces the risk of accidental needle-stick injuries. Needle puncture wounds can transmit blood-borne diseases such as Hepatitis B and AIDS. The ’311 and ’072 patented inventions effectively guard standard winged-needle-sets to prevent needle-stick injuries.

The ’311 patent claims a “slotted, locking guard for shielding a needle, and a winged needle assembly including a needle, a winged needle hub, and a slotted, locking guard.” This invention includes both “[a] slotted guard for locking a needle in a shielded position as the needle is removed from the patient”, and “a guarded winged needle assembly *** slidably mounted within the guard.” ...

...  

The alleged infringing device, made by ITL (an Australian company) sells under the name Platypus Needle Guard (Platypus). ITL manufactures the Platypus in Malaysia and Singapore. The Platypus needle guard is a “stand-alone” product: a small configured piece of plastic. This plastic guard structure is not attached to any other device. In other words, the Platypus does not include a needle, but only a sheathing structure. Some claims of the ’311 patent recite both a slotted guard and a guarded winged needle assembly. Before use, the Platypus resembles an open clamsshell (open-shell configuration). During use, the halves of the clam shell close to form the
needle guard (closed-shell configuration). ... The Platypus has an upper and a lower “jaw.” When closed, the upper jaw extends around and overlaps the inner, lower jaw. During use, a medical technician closes the Platypus and locks it around tubing connected to the winged needle assembly. When the technician removes the needle from a patient, the worker slides the guard down the tube until the needle assembly’s wings meet and pry the jaws apart. The wings and their attached needle assembly slide into and through the guard, forcing the jaws ever wider as the wings make their way into a notched opening at the guard’s back. Ultimately the wings slide into the rear opening. At that point, the jaws close around the used needle.

JMS is a large Japanese medical supply business that competes with MDS in the United States market. Beginning in June 1999, JMS purchased Platypus needle guards from ITL, entering into an agreement to distribute the Platypus worldwide (the Supply Agreement). Under the Supply Agreement, JMS bought open-shell configuration Platypus guard units from ITL in Singapore and Malaysia. JMS generally closed the Platypus guards around needle sets before distributing them to customers.

DSU alleges that the Platypus infringes the ’311 patent. DSU also alleges that JMS and ITL contributed to and induced each other’s infringement. JMS sought to sell ITL’s infringing Platypus until it could produce its substitute non-infringing product, the WingEater. ITL offered to supply its infringing Platypus. DSU additionally seeks damages from JMS because it “stole” MDS’s ability to renew a MasterGuard exclusive license with a former customer, Fresenius USA Mfg.

... III.

The jury found that JMS North America and JMS directly and contributorily infringed, and that JMS additionally induced JMS North America to infringe. However, the jury returned a verdict of non-infringement in favor of ITL. The jury entered a verdict finding that ITL did not engage in contributory infringement or inducement to infringe. The trial court denied DSU’s motion for new trial on the jury’s verdict that ITL did not contributorily infringe or induce infringement.

... B.

Resolution of Conflicting Precedent —
Section III.B., only, is considered en banc.

This court addresses Part III.B., of this opinion en banc. This section addresses, in the context of induced infringement, “the required intent *** to induce the specific acts of [infringement] or additionally to cause an infringement.” MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 n.4 (Fed. Cir. 2005). This section clarifies that intent requirement by holding en banc that, as was stated in Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 554 (Fed. Cir. 1990), “[t]he plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” The requirement that the alleged infringer knew or should have known his actions would induce actual infringement
necessarily includes the requirement that he or she knew of the patent. See *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1364 n.4 (Fed. Cir. 2006) (citing *Manville* and explaining that the inducing infringement standard was satisfied “because it is undisputed that [the alleged infringer] had notice of the patent”).

DSU claims the district court improperly instructed the jury on the state of mind necessary to prove inducement to infringe under 35 U.S.C. § 271(b). This court reviews the legal sufficiency of jury instructions on an issue of patent law without deference to the district court. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). This Court reviews jury instructions in their entirety and “only orders a new trial when errors in the instructions as a whole clearly mislead the jury.” *Delta-X Corp. v. Baker Hughes Prod. Tools, Inc.*, 984 F.2d 410, 415 (Fed. Cir. 1993)).

Under § 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). To establish liability under § 271(b), a patent holder must prove that once the defendants knew of the patent, they “actively and knowingly aid[ed] and abett[ed] another’s direct infringement.” *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis in original). However, “knowledge of the acts alleged to constitute infringement” is not enough. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003). The “mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Id.* at 1364 (citing *Manville*, 917 F.2d at 554).

DSU asked the court to instruct the jury, purportedly in accordance with *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464 (Fed. Cir. 1990), that to induce infringement, the inducer need only intend to cause the acts of the third party that constitute direct infringement. The trial court gave the following instruction to the jury:

In order to induce infringement, there must first be an act of direct infringement and proof that the defendant knowingly induced infringement with the intent to encourage the infringement. The defendant must have intended to cause the acts that constitute the direct infringement and must have known or should have known than[sic] its action would cause the direct infringement. Unlike direct infringement, which must take place within the United States, induced infringement does not require any activity by the indirect infringer in this country, as long as the direct infringement occurs here.

Transcript at 432. Thus, the court charged the jury in accordance with *Manville*. The statute does not define whether the purported infringer must intend to induce the infringement or whether the purported infringer must merely intend to engage in the acts that induce the infringement regardless of whether it knows it is causing another to infringe. DSU complains that the instruction is incorrect because it requires that the inducer possess specific intent to encourage another’s infringement,
and not merely that the inducer had knowledge of the acts alleged to constitute infringement.\(^2\)

In *Grokster*, which was a copyright case, the Supreme Court cited with approval this court’s decision in *Water Technologies* when it discussed inducement of infringement, stating:

> The rule on inducement of infringement as developed in the early cases is no different today. Evidence of “active steps *** taken to encourage direct infringement,” such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law’s reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use. *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005). As a result, if an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties. *Id.* at 937. “The inducement rule *** premises liability on purposeful, culpable expression and conduct.” *Id.*

*Grokster* thus validates this court’s articulation of the state of mind requirement for inducement. See *Manville*, 917 F.2d at 544. In *Manville*, this court held that the “alleged infringer must be shown *** to have knowingly induced infringement,” 917 F.2d at 553, not merely knowingly induced the acts that constitute direct infringement. This court explained its “knowing” requirement:

> It must be established that the defendant possessed specific intent to encourage another’s infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.

*Id.* at 553. In *Water Technologies*, also cited with approval by the Supreme Court, this court clarified: “While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice.” 850 F.2d at 668. Although this court stated “that proof of actual intent to cause the acts which constitute infringement is a necessary prerequisite to finding active inducement,” *Hewlett-Packard*, 909 F.2d at 1469, *Grokster* has clarified that the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement. In the words of a recent decision, inducement requires “that the alleged infringer knowingly induced infringement and possessed

\(^2\) In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990), this court stated that “[p]roof of actual intent to cause the acts which constitute infringement is a necessary prerequisite to finding active infringement.” DSU reads this statement as standing for the proposition that proof of intent to cause infringing acts is all that is required in order to establish inducement of infringement.
specific intent to encourage another’s infringement.” MEMC Elec., 420 F.3d at 1378 (Fed. Cir. 2005) (quoting Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another’s infringement, not merely that the inducer had knowledge of the direct infringer’s activities. Accordingly, the district court correctly instructed the jury in this case.

C.

The district court denied DSU’s motion for a new trial on the issue of inducement to infringe. This court reviews a denial of a motion for a new trial after a jury trial for abuse of discretion, affirming on any basis that supports the verdict. In denying the motion for new trial, the trial court stated:

Fundamental principles of law hold that it is up to the jury to make determinations of witness credibility, to decide the existence of any factual inferences, and to determine the weight to be attributed to any direct or indirect evidence. Although Plaintiffs introduced circumstantial evidence which permitted inferences of ITL’s intentions, it is up to the Jury to decide whether or not to draw any inference and to consider the weight of any such evidence. Assessing competing evidence is what the law asks juries to do, and the Court declines to take over this fundamental role of the Jury.

The jury heard evidence about the commercial transactions between ITL and JMS, including JMS’s intention to sell ITL’s Platypus to Fresenius until JMS could get its own WingEater approved by the Food & Drug Administration and ready for market. The jury also heard evidence that Mr. Utterberg’s lawyer informed ITL in January 1997 that the Platypus infringed the ’311 patent. Additionally, the jury learned that ITL contacted an Australian attorney, who concluded that its Platypus would not infringe. JMS and ITL then also obtained letters from U.S. patent counsel advising that the Platypus did not infringe. Mr. William Mobbs, one of the owners of ITL who had participated in the design of the Platypus, testified that ITL had no intent to infringe the ’311 patent.

Thus, on this record, the jury was well within the law to conclude that ITL did not induce JMS to infringe by purposefully and culpably encouraging JMS’s infringement. To the contrary, the record contains evidence that ITL did not believe its Platypus infringed. Therefore, it had no intent to infringe. Accordingly, the record supports the jury’s verdict based on the evidence showing a lack of the necessary specific intent. The trial court certainly did not abuse its discretion.

...
Alito, Justice:

We consider whether a party who “actively induces infringement of a patent” under 35 U.S.C. § 271(b) must know that the induced acts constitute patent infringement.

I

This case concerns a patent for an innovative deep fryer designed by respondent SEB S.A., a French maker of home appliances. In the late 1980’s, SEB invented a “cool-touch” deep fryer, that is, a deep fryer for home use with external surfaces that remain cool during the frying process. The cool-touch deep fryer consisted of a metal frying pot surrounded by a plastic outer housing. Attached to the housing was a ring that suspended the metal pot and insulated the housing from heat by separating it from the pot, creating air space between the two components. SEB obtained a U.S. patent for its design in 1991, and sometime later, SEB started manufacturing the cool-touch fryer and selling it in this country under its well-known “T-Fal” brand. Superior to other products in the American market at the time, SEB’s fryer was a commercial success.

In 1997, Sunbeam Products, Inc., a U.S. competitor of SEB, asked petitioner Pentalpha Enterprises, Ltd., to supply it with deep fryers meeting certain specifications. Pentalpha is a Hong Kong maker of home appliances and a wholly owned subsidiary of petitioner Global-Tech Appliances, Inc. [collectively “Pentalpha”].

In order to develop a deep fryer for Sunbeam, Pentalpha purchased an SEB fryer in Hong Kong and copied all but its cosmetic features. Because the SEB fryer bought in Hong Kong was made for sale in a foreign market, it bore no U.S. patent markings. After copying SEB’s design, Pentalpha retained an attorney to conduct a right-to-use study, but Pentalpha refrained from telling the attorney that its design was copied directly from SEB’s.

The attorney failed to locate SEB’s patent, and in August 1997 he issued an opinion letter stating that Pentalpha’s deep fryer did not infringe any of the patents that he had found. That same month, Pentalpha started selling its deep fryers to Sunbeam, which resold them in the United States under its trademarks. By obtaining its product from a manufacturer with lower production costs, Sunbeam was able to undercut SEB in the U.S. market.

After SEB’s customers started defecting to Sunbeam, SEB sued Sunbeam in March 1998, alleging that Sunbeam’s sales infringed SEB’s patent. Sunbeam notified Pentalpha of the lawsuit the following month. Undeterred, Pentalpha went on to sell deep fryers to Fingerhut Corp. and Montgomery Ward & Co., both of which resold them in the United States under their respective trademarks.

SEB settled the lawsuit with Sunbeam, and then sued Pentalpha, asserting two theories of recovery: First, SEB claimed that Pentalpha had directly infringed SEB’s patent in violation of 35 U.S.C. § 271(a), by selling or offering to sell its deep fryers; and second, SEB claimed that Pentalpha had contravened § 271(b) by actively
inducing Sunbeam, Fingerhut, and Montgomery Ward to sell or to offer to sell Pentalpha’s deep fryers in violation of SEB’s patent rights.

Following a 5-day trial, the jury found for SEB on both theories … . Pentalpha filed post-trial motions seeking a new trial or judgment as a matter of law … arguing, among other things, that there was insufficient evidence to support the jury’s finding of induced infringement under § 271(b) because Pentalpha did not actually know of SEB’s patent until it received the notice of the Sunbeam lawsuit in April 1998.

The District Court rejected Pentalpha’s argument, as did the Court of Appeals for the Federal Circuit, which affirmed the judgment. Summarizing a recent en banc decision, the Federal Circuit stated that induced infringement under § 271(b) requires a “plaintiff [to] show that the alleged infringer knew or should have known that his actions would induce actual infringements” and that this showing includes proof that the alleged infringer knew of the patent. Although the record contained no direct evidence that Pentalpha knew of SEB’s patent before April 1998, the court found adequate evidence to support a finding that “Pentalpha deliberately disregarded a known risk that SEB had a protective patent.” Such disregard, the court said, “is not different from actual knowledge, but is a form of actual knowledge.”

II

Pentalpha argues that active inducement liability under § 271(b) requires more than deliberate indifference to a known risk that the induced acts may violate an existing patent. Instead, Pentalpha maintains, actual knowledge of the patent is needed.

A

In assessing Pentalpha’s argument, we begin with the text of § 271(b)—which is short, simple, and, with respect to the question presented in this case, inconclusive. Section 271(b) states: “Whoever actively induces infringement of a patent shall be liable as an infringer.”

Although the text of § 271(b) makes no mention of intent, we infer that at least some intent is required. The term “induce” means “[t]o lead on; to influence; to prevail on; to move by persuasion or influence.” Webster’s New International Dictionary 1269 (2d ed. 1945). The addition of the adverb “actively” suggests that the inducement must involve the taking of affirmative steps to bring about the desired result, see id. at 27.

When a person actively induces another to take some action, the inducer obviously knows the action that he or she wishes to bring about. If a used car salesman induces a customer to buy a car, the salesman knows that the desired result is the purchase of the car. But what if it is said that the salesman induced the customer to buy a damaged car? Does this mean merely that the salesman induced the customer to purchase a car that happened to be damaged, a fact of which the salesman may have been unaware? Or does this mean that the salesman knew that the car was damaged? The statement that the salesman induced the customer to buy a damaged car is ambiguous.
So is § 271(b). In referring to a party that “induces infringement,” this provision may require merely that the inducer lead another to engage in conduct that happens to amount to infringement, i.e., the making, using, offering to sell, selling, or importing of a patented invention. See § 271(a). On the other hand, the reference to a party that “induces infringement” may also be read to mean that the inducer must persuade another to engage in conduct that the inducer knows is infringement. Both readings are possible.

B

Finding no definitive answer in the statutory text, we turn to the case law that predates the enactment of § 271 as part the Patent Act of 1952. As we recognized in *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964) (*Aro II*), “[t]he section was designed to ‘codify in statutory form principles of contributory infringement’ which had been ‘part of our law for about 80 years.’” *Id.* at 485-486, n. 6 (quoting H.R. Rep. No. 1923, 82d Cong., 2d Sess., 9 (1952)).

Unfortunately, the relevant pre-1952 cases are less clear than one might hope with respect to the question presented here. Before 1952, both the conduct now covered by § 271(b) (induced infringement) and the conduct now addressed by § 271(c) (sale of a component of a patented invention) were viewed as falling within the overarching concept of “contributory infringement.” Cases in the latter category—i.e., cases in which a party sold an item that was not itself covered by the claims of a patent but that enabled another party to make or use a patented machine, process, or combination—were more common.

The pre-1952 case law provides conflicting signals regarding the intent needed in such cases. In an oft-cited decision, then-Judge Taft suggested that it was sufficient if the seller of the component part intended that the part be used in an invention that happened to infringe a patent. He wrote that it was “well settled that where one makes and sells one element of a combination covered by a patent with the intention and for the purpose of bringing about its use in such a combination he is guilty of contributory infringement.” *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 721 (6th Cir. 1897).

On the other hand, this Court, in *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), overruled on other grounds, *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917), stated that “if the defendants [who were accused of contributory infringement] knew of the patent and that [the direct infringer] had unlawfully made the patented article *** with the intent and purpose that [the direct infringer] should use the infringing article *** they would assist in her infringing use.” 224 U.S. at 33 (emphasis added and deleted). Our decision in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), which looked to the law of contributory patent infringement for guidance in determining the standard to be applied in a case claiming contributory copyright infringement, contains dicta that may be read as interpreting the pre-1952 cases this way. In *Grokster*, we said that “[t]he

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2 Direct infringement has long been understood to require no more than the unauthorized use of a patented invention. Thus, a direct infringer’s knowledge or intent is irrelevant.
inducement rule *** premises liability on purposeful, culpable expression and conduct.” *Id.* at 937.

While both the language of § 271(b) and the pre-1952 case law that this provision was meant to codify are susceptible to conflicting interpretations, our decision in *Aro II* resolves the question in this case. In *Aro II*, a majority held that a violator of § 271(c) must know “that the combination for which his component was especially designed was both patented and infringing,” 377 U.S. at 488, and as we explain below, that conclusion compels this same knowledge for liability under § 271(b).

C

As noted above, induced infringement was not considered a separate theory of indirect liability in the pre-1952 case law. Rather, it was treated as evidence of “contributory infringement,” that is, the aiding and abetting of direct infringement by another party. When Congress enacted § 271, it separated what had previously been regarded as contributory infringement into two categories, one covered by § 271(b) and the other covered by § 271(c).

*Aro II* concerned § 271(c), which states in relevant part:

> Whoever offers to sell or sells *** a component of a patented [invention] ***, constituting a material part of the invention, *knowing the same to be especially made or especially adapted for use in an infringement of such* patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(Emphasis added). This language contains exactly the same ambiguity as § 271(b). The phrase “knowing [a component] to be especially made or especially adapted for use in an infringement” may be read to mean that a violator must know that the component is “especially adapted for use” in a product that happens to infringe a patent. Or the phrase may be read to require, in addition, knowledge of the patent’s existence.

This question closely divided the *Aro II* Court. In a badly fractured decision, a majority concluded that knowledge of the patent was needed. 377 U.S. at 488 & n. 8; *id.* at 514 (White, J., concurring); *id.* at 524-527 (Black, J., dissenting). Justice Black’s opinion, which explained the basis for the majority’s view, concluded that the language of § 271(c) supported this interpretation. *See id.* at 525. His opinion also relied on an amendment to this language that was adopted when the bill was in committee. *Id.* at 525-527.

Four Justices disagreed with this interpretation and would have held that a violator of § 271(c) need know only that the component is specially adapted for use in a product that happens to infringe a patent. *See id.* at 488-490, n. 8. These Justices

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5 Although Justice Black disagreed with the judgment and was thus in dissent, he was in the majority with respect to the interpretation of § 271(c), and his opinion sets out the reasoning of the majority on this point. Three other Justices joined his opinion, and a fourth, Justice White, endorsed his reasoning with respect to the interpretation of § 271(c). *See* 377 U.S. at 514 (White, J., concurring).
thought that this reading was supported by the language of § 271(c) and the pre-1952 case law, and they disagreed with the inference drawn by the majority from the amendment of § 271(c)’s language.

While there is much to be said in favor of both views expressed in Aro II, the “holding in Aro II has become a fixture in the law of contributory infringement under § 271(c),” 5 R. Moy, Walker on Patents § 15:20, p. 15-131 (4th ed. 2009)—so much so that SEB has not asked us to overrule it. Nor has Congress seen fit to alter § 271(c)’s intent requirement in the nearly half a century since Aro II was decided. In light of the “‘special force’” of the doctrine of stare decisis with regard to questions of statutory interpretation, see John R. Sand & Gravel Co. v. United States, 552 U.S. 130, 139 (2008), we proceed on the premise that § 271(c) requires knowledge of the existence of the patent that is infringed.

Based on this premise, it follows that the same knowledge is needed for induced infringement under § 271(b). As noted, the two provisions have a common origin in the pre-1952 understanding of contributory infringement, and the language of the two provisions creates the same difficult interpretive choice. It would thus be strange to hold that knowledge of the relevant patent is needed under § 271(c) but not under § 271(b).

Accordingly, we now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement.

III

Returning to Pentalpha’s principal challenge, we agree that deliberate indifference to a known risk that a patent exists is not the appropriate standard under § 271(b). We nevertheless affirm the judgment of the Court of Appeals because the evidence in this case was plainly sufficient to support a finding of Pentalpha’s knowledge under the doctrine of willful blindness.

A

The doctrine of willful blindness is well established in criminal law. Many criminal statutes require proof that a defendant acted knowingly or willfully, and courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances. The traditional rationale for this doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge. Edwards, The Criminal Degrees of Knowledge, 17 Mod. L. Rev. 294, 302 (1954) (hereinafter Edwards) (observing on the basis of English authorities that “up to the present day, no real doubt has been cast on the proposition that [willful blindness] is as culpable as actual knowledge”). It is also said that persons who know enough to blind themselves to direct proof of critical facts in effect have actual knowledge of those facts. See United States v. Jewell, 532 F.2d 697, 700 (9th Cir. 1976) (en banc).
This Court’s opinion more than a century ago in *Spurr v. United States*, 174 U.S. 728 (1899), while not using the term “willful blindness,” endorsed a similar concept. The case involved a criminal statute that prohibited a bank officer from “willfully” certifying a check drawn against insufficient funds. We said that a willful violation would occur “if the [bank] officer purposely keeps himself in ignorance of whether the drawer has money in the bank.” *Id.* at 735. Following our decision in *Spurr*, several federal prosecutions in the first half of the 20th century invoked the doctrine of willful blindness. Later, a 1962 proposed draft of the Model Penal Code, which has since become official, attempted to incorporate the doctrine by defining “knowledge of the existence of a particular fact” to include a situation in which “a person is aware of a high probability of [the fact’s] existence, unless he actually believes that it does not exist.” ALI, *Model Penal Code* § 2.02(7) (Proposed Official Draft 1962). Our Court has used the Code’s definition as a guide in analyzing whether certain statutory presumptions of knowledge comported with due process. *See Turner v. United States*, 396 U.S. 398, 416-417 (1970); *Leary v. United States*, 395 U.S. 6, 46-47 & n. 93 (1969). And every Court of Appeals—with the possible exception of the District of Columbia Circuit—has fully embraced willful blindness, applying the doctrine to a wide range of criminal statutes.

Given the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b).

Pentalpha urges us not to take this step, arguing that § 271(b) demands more than willful blindness with respect to the induced acts that constitute infringement. This question, however, is not at issue here. There is no need to invoke the doctrine of willful blindness to establish that Pentalpha knew that the retailers who purchased its fryer were selling that product in the American market; Pentalpha was indisputably aware that its customers were selling its product in this country.

Pentalpha further contends that this Court in *Grokster* did not accept the Solicitor General’s suggestion that Grokster and StreamCast could be held liable for inducing the infringement of copyrights under a theory of willful blindness. But the Court had no need to consider the doctrine of willful blindness in that case because

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6 The doctrine emerged in English law almost four decades earlier and became firmly established by the end of the 19th century. Edwards 298-301. In American law, one of the earliest references to the doctrine appears in an 1882 jury charge in a federal prosecution. In the charge, the trial judge rejected the “great misapprehension” that a person may “close his eyes, when he pleases, upon all sources of information, and then excuse his ignorance by saying that he does not see anything.” *See United States v. Houghton*, 14 F. 544, 547 (D.N.J. 1882).

8 Unlike the dissent, we do not think that utilitarian concerns demand a stricter standard for knowledge under § 271(b). The dissent does not explain—nor can we see—why promoting “the Progress of Science and useful Arts” requires protecting parties who actively encourage others to violate patent rights and who take deliberate steps to remain ignorant of those rights despite a high probability that the rights exist and are being infringed.
the Court found ample evidence that Grokster and StreamCast were fully aware—in the ordinary sense of the term—that their file-sharing software was routinely used in carrying out the acts that constituted infringement (the unauthorized sharing of copyrighted works) and that these acts violated the rights of copyright holders. See 545 U.S. at 922-927, 937-940.

B

While the Courts of Appeals articulate the doctrine of willful blindness in slightly different ways, all appear to agree on two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence. Under this formulation, a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts. See G. Williams, Criminal Law § 57, p. 159 (2d ed. 1961) (“A court can properly find willful blindness only where it can almost be said that the defendant actually knew”). By contrast, a reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing, see ALI, Model Penal Code § 2.02(2)(c) (1985), and a negligent defendant is one who should have known of a similar risk but, in fact, did not, see § 2.02(2)(d).

The test applied by the Federal Circuit in this case departs from the proper willful blindness standard in two important respects. First, it permits a finding of knowledge when there is merely a “known risk” that the induced acts are infringing. Second, in demanding only “deliberate indifference” to that risk, the Federal Circuit’s test does not require active efforts by an inducer to avoid knowing about the infringing nature of the activities.

In spite of these flaws, we believe that the evidence when viewed in the light most favorable to the verdict for SEB is sufficient under the correct standard. The jury could have easily found that before April 1998 Pentalpha willfully blinded itself to the infringing nature of the sales it encouraged Sunbeam to make.10

SEB’s cool-touch fryer was an innovation in the U.S. market when Pentalpha copied it. As one would expect with any superior product, sales of SEB’s fryer had been growing for some time. Pentalpha knew all of this, for its CEO and president, John Sham, testified that, in developing a product for Sunbeam, Pentalpha performed “market research” and “gather[ed] information as much as possible.” Pentalpha’s belief that SEB’s fryer embodied advanced technology that would be valuable in the U.S. market is evidenced by its decision to copy all but the cosmetic features of SEB’s fryer.

10 The District Court did not instruct the jury according to the standard we set out today, and Pentalpha asks us to remand the case so it can move for a new trial. We reject that request. Pentalpha did not challenge the jury instructions in the Court of Appeals, and that court did not pass upon the issue. Finding no “exceptional” circumstances in this case, we follow our usual course and refuse to consider the issue. See Youakim v. Miller, 425 U.S. 231, 234 (1976) (per curiam).
Also revealing is Pentalpha’s decision to copy an overseas model of SEB’s fryer. Pentalpha knew that the product it was designing was for the U.S. market, and Sham—himself a named inventor on numerous U.S. patents—was well aware that products made for overseas markets usually do not bear U.S. patent markings. Even more telling is Sham’s decision not to inform the attorney from whom Pentalpha sought a right-to-use opinion that the product to be evaluated was simply a knockoff of SEB’s deep fryer. On the facts of this case, we cannot fathom what motive Sham could have had for withholding this information other than to manufacture a claim of plausible deniability in the event that his company was later accused of patent infringement. Nor does Sham’s testimony on this subject provide any reason to doubt that inference. Asked whether the attorney would have fared better had he known of SEB’s design, Sham was nonresponsive. All he could say was that a patent search is not an “easy job” and that is why he hired attorneys to perform them.

Taken together, this evidence was more than sufficient for a jury to find that Pentalpha subjectively believed there was a high probability that SEB’s fryer was patented, that Pentalpha took deliberate steps to avoid knowing that fact, and that it therefore willfully blinded itself to the infringing nature of Sunbeam’s sales.

...Kennedy, Justice, dissenting:

The Court is correct, in my view, to conclude that 35 U.S.C. § 271(b) must be read in tandem with § 271(c), and therefore that to induce infringement a defendant must know “the induced acts constitute patent infringement.”

Yet the Court does more. Having interpreted the statute to require a showing of knowledge, the Court holds that willful blindness will suffice. This is a mistaken step. Willful blindness is not knowledge; and judges should not broaden a legislative proscription by analogy. See United States v. Jewell, 532 F.2d 697, 706 (9th Cir. 1976) (en banc) (Kennedy, J., dissenting) (“When a statute specifically requires knowledge as an element of a crime, however, the substitution of some other state of mind cannot be justified even if the court deems that both are equally blameworthy.”). In my respectful submission, the Court is incorrect in the definition it now adopts; but even on its own terms the Court should remand to the Court of Appeals to consider in the first instance whether there is sufficient evidence of knowledge to support the jury’s finding of inducement.

The Court invokes willful blindness to bring those who lack knowledge within § 271(b)’s prohibition. The Court’s definition of willful blindness reveals this basic purpose. One can believe that there is a “high probability” that acts might infringe a patent but nonetheless conclude they do not infringe. The alleged inducer who believes a device is noninfringing cannot be said to know otherwise.

The Court justifies its substitution of willful blindness for the statutory knowledge requirement in two ways, neither of which is convincing.

First, the Court appeals to moral theory by citing the “traditional rationale” that willfully blind defendants “are just as culpable as those who have actual knowledge.” But the moral question is a difficult one. Is it true that the lawyer who
knowingly suborns perjury is no more culpable than the lawyer who avoids learning that his client, a criminal defendant, lies when he testifies that he was not the shooter? See Hellman, Willfully Blind for Good Reason, 3 Crim. L. & Phil. 301, 305-308 (2009); Luban, Contrived Ignorance, 87 Geo. L.J. 957 (1999). The answer is not obvious. Perhaps the culpability of willful blindness depends on a person’s reasons for remaining blind. Or perhaps only the person’s justification for his conduct is relevant. This is a question of morality and of policy best left to the political branches. Even if one were to accept the substitution of equally blameworthy mental states in criminal cases in light of the retributive purposes of the criminal law, those purposes have no force in the domain of patent law that controls in this case. The Constitution confirms that the purpose of the patent law is a utilitarian one, to “promote the Progress of Science and useful Arts,” Art. I, § 8, cl. 8.

Second, the Court appeals to precedent, noting that a “similar concept” to willful blindness appears in this Court’s cases as early as 1899. But this Court has never before held that willful blindness can substitute for a statutory requirement of knowledge. Spurr v. United States, 174 U.S. 728, 735 (1899), explained that “evil design may be presumed if the [bank] officer purposefully keeps himself in ignorance of whether the drawer has money in the bank or not, or is grossly indifferent to his duty in respect to the ascertaining of that fact.” The question in Spurr was whether the defendant’s admitted violation was willful, and with this sentence the Court simply explained that wrongful intent may be inferred from the circumstances. It did not suggest that blindness can substitute for knowledge. Neither did Turner v. United States, 396 U.S. 398 (1970), or Leary v. United States, 395 U.S. 6 (1969). As the Court here explains, both cases held only that certain statutory presumptions of knowledge were consistent with due process. And although most Courts of Appeals have embraced willful blindness, counting courts in a circuit split is not this Court’s usual method for deciding important questions of law.

The Court appears to endorse the willful blindness doctrine here for all federal criminal cases involving knowledge. It does so in a civil case where it has received no briefing or argument from the criminal defense bar, which might have provided important counsel on this difficult issue.

There is no need to invoke willful blindness for the first time in this case. Facts that support willful blindness are often probative of actual knowledge. Circumstantial facts like these tend to be the only available evidence in any event, for the jury lacks direct access to the defendant’s mind. The jury must often infer knowledge from conduct, and attempts to eliminate evidence of knowledge may justify such inference, as where an accused inducer avoids further confirming what he already believes with good reason to be true. The majority’s decision to expand the statute’s scope appears to depend on the unstated premise that knowledge requires certainty, but the law often permits probabilistic judgments to count as knowledge.

The instant dispute provides a case in point. Pentalpha copied an innovative fryer. The model it copied bore no U.S. patent markings, but that could not have been a surprise, for Pentalpha knew that a fryer purchased in Hong Kong was unlikely to bear such markings. And Pentalpha failed to tell the lawyer who ran a patent search...
that it copied the SEB fryer. These facts may suggest knowledge that Pentalpha’s fryers were infringing, and perhaps a jury could so find.

But examining the sufficiency of the evidence presented in the 5-day trial requires careful review of an extensive record. The trial transcript alone spans over 1,000 pages. If willful blindness is as close to knowledge and as far from the “knew or should have known” jury instruction provided in this case as the Court suggests, then reviewing the record becomes all the more difficult. I would leave that task to the Court of Appeals in the first instance on remand.

For these reasons, and with respect, I dissent.

Limelight Networks, Inc. v. Akamai Techs., Inc.
134 S. Ct. 2111 (2014)

Alito, Justice:

This case presents the question whether a defendant may be liable for inducing infringement of a patent under 35 U.S.C. § 271(b) when no one has directly infringed the patent under § 271(a) or any other statutory provision. The statutory text and structure and our prior case law require that we answer this question in the negative. We accordingly reverse the Federal Circuit, which reached the opposite conclusion.

I

A

Respondent the Massachusetts Institute of Technology is the assignee of U.S. Patent No. 6,108,703, which claims a method of delivering electronic data using a “content delivery network,” or “CDN.” Respondent Akamai Technologies, Inc., is the exclusive licensee. Akamai maintains many servers distributed in various locations. Proprietors of Web sites, known as “content providers,” contract with Akamai to deliver their Web sites’ content to individual Internet users. The ’703 patent provides for the designation of certain components of a content provider’s Web site (often large files, such as video or music files) to be stored on Akamai’s servers and accessed from those servers by Internet users. The process of designating components to be stored on Akamai’s servers is known as “tagging.” By “aggregat[ing] the data demands of multiple content providers with differing peak usage patterns and serv[ing] that content from multiple servers in multiple locations,” 614 F. Supp. 2d 90, 96 (D. Mass. 2009), as well as by delivering content from servers located in the same geographic area as the users who are attempting to access it, Akamai is able to increase the speed with which Internet users access the content of its customers’ Web sites.

Petitioner Limelight Networks, Inc., also operates a CDN and carries out several of the steps claimed in the ’703 patent. But instead of tagging those components of its customers’ Web sites that it intends to store on its servers (a step included in the ’703 patent), Limelight requires its customers to do their own tagging. Respondents claim that Limelight “provides instructions and offers technical assistance” to its customers regarding how to tag, 629 F.3d 1311, 1321 (Fed. Cir.
but the record is undisputed that Limelight does not tag the components to be stored on its servers.

B

In 2006, respondents sued Limelight … claiming patent infringement. The case was tried to a jury, which found that Limelight had committed infringement and awarded more than $40 million in damages.

Respondents’ victory was short-lived, however. After the jury returned its verdict, the Federal Circuit decided *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008). In that case the Court of Appeals rejected a claim that the defendant’s method, involving bidding on financial instruments using a computer system, directly infringed the plaintiff’s patent. The defendant performed some of the steps of the patented method, and its customers, to whom the defendant gave access to its system along with instructions on the use of the system, performed the remaining steps. The court started from “the proposition that direct infringement requires a single party to perform every step of a claimed method.” *Id.* at 1329. This requirement is satisfied even though the steps are actually undertaken by multiple parties, the court explained, if a single defendant “exercises ‘control or direction’ over the entire process such that every step is attributable to the controlling party.” *Id.* The court held that the defendant in *Muniauction* was not liable for direct infringement because it did not exercise control or direction over its customers’ performance of those steps of the patent that the defendant itself did not perform. *Id.* at 1330.

In light of *Muniauction*, Limelight moved for reconsideration of its earlier motion for judgment as a matter of law, which the District Court had denied. The District Court granted the motion, concluding that *Muniauction* precluded a finding of direct infringement under § 271(a) because infringement of the ’703 patent required tagging and Limelight does not control or direct its customers’ tagging. A panel of the Federal Circuit affirmed, explaining that a defendant that does not itself undertake all of a patent’s steps can be liable for direct infringement only “when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps.” 629 F.3d at 1320. Since neither of these conditions was met in the present case, the Federal Circuit panel held that Limelight could not be held liable for direct infringement. *Id.*

The Federal Circuit granted en banc review and reversed. The en banc court found it unnecessary to revisit its § 271(a) direct infringement case law. Instead, it concluded that the “evidence could support a judgment in [respondents’] favor on a theory of induced infringement” under § 271(b). 692 F.3d 1301, 1319 (Fed. Cir. 2012) (per curiam). This was true, the court explained, because § 271(b) liability arises when a defendant carries out some steps constituting a method patent and encourages others to carry out the remaining steps—even if no one would be liable as a direct infringer in such circumstances, because those who performed the remaining steps did not act as agents of, or under the direction or control of, the defendant. The Court of Appeals did not dispute that “there can be no indirect infringement without direct infringement,” *id.* at 1308, but it explained that “[r]e-
quiring proof that there has been direct infringement *** is not the same as requiring proof that a single party would be liable as a direct infringer,”[1] id. at 1308-1309. …

Limelight sought certiorari, which we granted. …

II

A

Neither the Federal Circuit, see 692 F.3d at 1308, nor respondents, see Tr. of Oral Arg. 44, dispute the proposition that liability for inducement must be predicated on direct infringement. This is for good reason, as our case law leaves no doubt that inducement liability may arise “if, but only if, [there is] *** direct infringement.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961).

One might think that this simple truth is enough to dispose of this appeal. But the Federal Circuit reasoned that a defendant can be liable for inducing infringement under § 271(b) even if no one has committed direct infringement within the terms of § 271(a) (or any other provision of the patent laws), because direct infringement can exist independently of a violation of these statutory provisions.

The Federal Circuit’s analysis fundamentally misunderstands what it means to infringe a method patent.[‡] A method patent claims a number of steps; under this Court’s case law, the patent is not infringed unless all the steps are carried out. See, e.g., *Aro*, 365 U.S. at 344 (a “patent covers only the totality of the elements in the claim and *** no element, separately viewed, is within the grant”). This principle follows ineluctably from what a patent is: the conferral of rights in a particular claimed set of elements. “Each element contained in a patent claim is deemed material to defining the scope of the patented invention,” *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997), and a patentee’s rights extend only to the claimed combination of elements, and no further.

The Federal Circuit held in *Muniauction* that a method’s steps have not all been performed as claimed by the patent unless they are all attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them. See 532 F.3d at 1329-1330. Assuming without deciding that the Federal Circuit’s holding in *Muniauction* is correct, there has simply been no infringement of the method in which respondents have staked out an interest, because the performance of all the patent’s steps is not attributable to any one person. And, as both the Federal Circuit and respondents admit, where there has been no direct infringement, there can be no inducement of infringement under § 271(b).

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[2] *Aro* addressed contributory infringement under § 271(c), rather than inducement of infringement under § 271(b), but we see no basis to distinguish for these purposes between the two, which after all spring from common stock. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067-2068 (2011).

[3] *Ed. Note: Ouch!*
The Federal Circuit’s contrary view would deprive § 271(b) of ascertainable standards. If a defendant can be held liable under § 271(b) for inducing conduct that does not constitute infringement, then how can a court assess when a patent holder’s rights have been invaded? What if a defendant pays another to perform just one step of a 12-step process, and no one performs the other steps, but that one step can be viewed as the most important step in the process? In that case the defendant has not encouraged infringement, but no principled reason prevents him from being held liable for inducement under the Federal Circuit’s reasoning, which permits inducement liability when fewer than all of a method’s steps have been performed within the meaning of the patent. The decision below would require the courts to develop two parallel bodies of infringement law: one for liability for direct infringement, and one for liability for inducement.

Section 271(f)(1) reinforces our reading of § 271(b). That subsection imposes liability on a party who “supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention *** in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States” (emphasis added). As this provision illustrates, when Congress wishes to impose liability for inducing activity that does not itself constitute direct infringement, it knows precisely how to do so. The courts should not create liability for inducement of noninfringing conduct where Congress has elected not to extend that concept.

The Federal Circuit seems to have adopted the view that Limelight induced infringement on the theory that the steps that Limelight and its customers perform would infringe the ’703 patent if all the steps were performed by the same person. But we have already rejected the notion that conduct which would be infringing in altered circumstances can form the basis for contributory infringement, and we see no reason to apply a different rule for inducement. In *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), a manufacturer produced components of a patented machine and then exported those components overseas to be assembled by its foreign customers.4 (The assembly by the foreign customers did not violate U.S. patent laws.) In both *Deepsouth* and this case, the conduct that the defendant induced or contributed to would have been infringing if committed in altered circumstances: in *Deepsouth* if the machines had been assembled in the United States, see id. at 526, and in this case if performance of all of the claimed steps had been attributable to the same person. In *Deepsouth*, we rejected the possibility of contributory infringement because the machines had not been assembled in the United States, and direct infringement had consequently never occurred. See id. at 526-527. Similarly, in this case, performance of all the claimed steps cannot be attributed to a single person, so direct infringement never occurred. Limelight cannot be liable for inducing infringement that never came to pass.

\footnote{Section 271(f) now prohibits the exporter’s conduct at issue in *Deepsouth*.}
B

Respondents’ arguments in support of the Federal Circuit’s reading of the statute are unpersuasive. First, respondents note that tort law imposes liability on a defendant who harms another through a third party, even if that third party would not himself be liable, and respondents contend that, given the background tort principles against which the Patent Act of 1952 was enacted, it should not matter that no one is liable for direct infringement in this case. But the reason Limelight could not have induced infringement under § 271(b) is not that no third party is liable for direct infringement; the problem, instead, is that no direct infringement was committed. Muniauction (which, again, we assume to be correct) instructs that a method patent is not directly infringed—and the patentee’s interest is thus not violated—unless a single actor can be held responsible for the performance of all steps of the patent. Because Limelight did not undertake all steps of the ’703 patent and cannot otherwise be held responsible for all those steps, respondents’ rights have not been violated. Unsurprisingly, respondents point us to no tort case in which liability was imposed because a defendant caused an innocent third party to undertake action that did not violate the plaintiff’s legal rights.

In a related argument, respondents contend that, at tort, liability sometimes attaches where two or more defendants inflict injury, even if each defendant’s conduct, standing alone, would not be actionable. See W. Keeton et al., Prosser and Keeton on Torts § 52, at 354 (5th ed. 1984) (multiple defendants who each add negligible impurities to stream liable if aggregate impurities cause harm). But the rationale for imposing liability in these circumstances is that the defendants collectively invaded the plaintiff’s protected interests. By contrast, under the Muniauction rule, respondents’ interests in the ’703 patent have not been invaded.

Second, respondents seek to analogize § 271(b) to the federal aiding and abetting statute, 18 U.S.C. § 2, and they argue that two parties who divide all the necessary elements of a crime between them are both guilty under § 2. The analogy does not hold up. The aiding and abetting statute must be read “against its common-law background,” Standefer v. United States, 447 U.S. 10, 19 (1980), and at common law two or more defendants, each of whom committed an element of a crime, were liable as principals. See, e.g., 1 J. Bishop, Commentaries on the Criminal Law § 649, at 392 (7th ed. 1882). While we have drawn on criminal law concepts in the past in interpreting § 271(b), see Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068-2070 (2011), we think it unlikely that Congress had this particular doctrine in mind when it enacted the Patent Act of 1952, given the doctrine’s inconsistency with the Act’s cornerstone principle that patentees have a right only to the set of elements claimed in their patents and nothing further.

Third, respondents contend that patent law principles established before the enactment of the Patent Act demonstrate that a defendant that performs some steps of a patent with the purpose of having its customers perform the remaining steps is liable for inducing infringement. But here, too, the nature of the rights created by the Patent Act defeats the notion that Congress could have intended to permit inducement liability where there is no underlying direct infringement. According to respondents, their understanding of the pre-1952 doctrine casts doubt on the
Muniauction rule for direct infringement under § 271(a), on the ground that that rule has the indirect effect of preventing inducement liability where Congress would have wanted it. But the possibility that the Federal Circuit erred by too narrowly circumscribing the scope of § 271(a) is no reason for this Court to err a second time by misconstruing § 271(b) to impose liability for inducing infringement where no infringement has occurred.

Finally, respondents, like the Federal Circuit, criticize our interpretation of § 271(b) as permitting a would-be infringer to evade liability by dividing performance of a method patent’s steps with another whom the defendant neither directs nor controls. We acknowledge this concern. Any such anomaly, however, would result from the Federal Circuit’s interpretation of § 271(a) in Muniauction. A desire to avoid Muniauction’s natural consequences does not justify fundamentally altering the rules of inducement liability that the text and structure of the Patent Act clearly require—an alteration that would result in its own serious and problematic consequences, namely, creating for § 271(b) purposes some free-floating concept of “infringement” both untethered to the statutory text and difficult for the lower courts to apply consistently.

III

Respondents ask us to review the merits of the Federal Circuit’s Muniauction rule for direct infringement under § 271(a). We decline to do so today.

In the first place, the question presented is clearly focused on § 271(b), not § 271(a). We granted certiorari on the following question: “Whether the Federal Circuit erred in holding that a defendant may be held liable for inducing patent infringement under 35 U.S.C. § 271(b) even though no one has committed direct infringement under § 271(a).” Pet. for Cert. i. The question presupposes that Limelight has not committed direct infringement under § 271(a). And since the question on which we granted certiorari did not involve § 271(a), petitioner did not address that important issue in its opening brief. Our decision on the § 271(b) question necessitates a remand to the Federal Circuit, and on remand, the Federal Circuit will have the opportunity to revisit the § 271(a) question if it so chooses.

IV

The judgment below is reversed, and the case is remanded for further proceedings consistent with this opinion.

Editor’s Note

On remand, the Federal Circuit—in a sharply divided opinion—adhered to the view that there was no direct infringement in the case because neither Limelight nor its customers performed all the steps of the claimed methods. Akamai Techs., Inc. v. Limelight Networks, Inc., __ F.3d __, 2015 WL 2216261 (Fed. Cir. May 13, 2015).
A patent holder, and the holder’s lawful licensees, can recover for monetary injury when their exclusive rights are violated by others’ wrongful conduct. One form of patent injury occurs if unauthorized persons or entities copy, use, or otherwise infringe upon the patented invention. Another form of injury to the patent holder or his licensees can occur when the actor induces others to infringe the patent. In the instant case, both forms of injury—direct infringement and wrongful inducement of others to commit infringement—were alleged. After two trials, the defendant was found liable for both types of injury. The dispute now before the Court concerns the inducement aspect of the case.

I

The patent holder who commenced this action is the petitioner here, Commil. The technical details of Commil’s patent are not at issue. So it suffices to say, with much oversimplification, that the patent is for a method of implementing short-range wireless networks. Suppose an extensive business headquarters or a resort or a college campus wants a single, central wireless system (sometimes called a Wi-Fi network). In order to cover the large space, the system needs multiple base stations so a user can move around the area and still stay connected. Commil’s patent relates to a method of providing faster and more reliable communications between devices and base stations. …

Commil brought this action against Cisco Systems, which makes and sells wireless networking equipment. … Commil alleged that Cisco had infringed Commil’s patent by making and using networking equipment. In addition Commil alleged that Cisco had induced others to infringe the patent by selling the infringing equipment for them to use, in contravention of Commil’s exclusive patent rights.

At the first trial, the jury concluded that Commil’s patent was valid and that Cisco had directly infringed. The jury awarded Commil $3.7 million in damages. As to induced infringement, the jury found Cisco not liable. Commil filed a motion for a new trial on induced infringement and damages, which the District Court granted because of certain inappropriate comments Cisco’s counsel had made during the first trial.

A month before the second trial Cisco went to the [PTO] asked it to reexamine the validity of Commil’s patent. The Office granted the request; but, undoubtedly to Cisco’s disappointment, it confirmed the validity of Commil’s patent.

Back in the District Court, the second trial proceeded, limited to the issues of inducement and damages on that issue and direct infringement. As a defense to the claim of inducement, Cisco argued it had a good-faith belief that Commil’s patent was invalid. It sought to introduce evidence to support that assertion. The District Court, however, ruled that Cisco’s proffered evidence of its good-faith belief in the patent’s invalidity was inadmissible. While the District Court’s order does not provide the reason for the ruling, it seems the court excluded this evidence on the as-
The presumption that belief in invalidity is not a defense to a plaintiff’s claim that the defendant induced others to infringe.

At the close of trial, and over Cisco’s objection, the District Court instructed the jury that it could find inducement if “Cisco actually intended to cause the acts that constitute *** direct infringement and that Cisco knew or should have known that its actions would induce actual infringement.” The jury returned a verdict for Commil on induced infringement and awarded $63.7 million in damages.

After the verdict, but before judgment, this Court issued its decision in Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060 (2011). That case, as will be discussed in more detail, held that, in an action for induced infringement, it is necessary for the plaintiff to show that the alleged inducer knew of the patent in question and knew the induced acts were infringing. Relying on that case, Cisco again urged that the jury instruction was incorrect because it did not state knowledge as the governing standard for inducement liability. The District Court denied Cisco’s motion and entered judgment in Commil’s favor.

Cisco appealed … . The Court of Appeals affirmed in part, vacated in part, and remanded for further proceedings. The court concluded it was error for the District Court to have instructed the jury that Cisco could be liable for induced infringement if it “‘knew or should have known’” that its customers infringed. … By stating that Cisco could be found liable if it “‘knew or should have known that its actions would induce actual infringement,’” the Court of Appeals explained, the District Court had allowed “the jury to find [Cisco] liable based on mere negligence where knowledge is required.” That ruling, which requires a new trial on the inducement claim with a corrected instruction on knowledge, is not in question here.

What is at issue is the second holding of the Court of Appeals, addressing Cisco’s contention that the trial court committed further error in excluding Cisco’s evidence that it had a good-faith belief that Commil’s patent was invalid. Beginning with the observation that it is “axiomatic that one cannot infringe an invalid patent,” the Court of Appeals reasoned that “evidence of an accused inducer’s good-faith belief of invalidity may negate the requisite intent for induced infringement.” The court saw “no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement for the purpose of whether a defendant possessed the specific intent to induce infringement of a patent.”

II

Although the precise issue to be addressed concerns a claim of improper inducement to infringe, the discussion to follow refers as well to direct infringement and contributory infringement, so it is instructive at the outset to set forth the statutory provisions pertaining to these three forms of liability. These three relevant provisions are found in § 271 of the Patent Act.

Subsection (a) governs direct infringement … . Under this form of liability, a defendant’s mental state is irrelevant. Direct infringement is a strict-liability offense. Global-Tech, 131 S. Ct. at 2065 n. 2.
Subsection (b) governs induced infringement ... . In contrast to direct infringement, liability for inducing infringement attaches only if the defendant knew of the patent and that "the induced acts constitute patent infringement." *Id.* at 2068. In Commil and the Government's view, not only is knowledge or belief in the patent's validity irrelevant, they further argue the party charged with inducing infringement need not know that the acts it induced would infringe. On this latter point, they are incorrect, as will be explained below.

Subsection (c) deals with contributory infringement ... . Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement. *Aro Mfg. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964) (*Aro II*).

This case asks a question of first impression: whether knowledge of, or belief in, a patent's validity is required for induced infringement under § 271(b).

A

Before turning to the question presented, it is necessary to reaffirm what the Court held in *Global-Tech*. Commil and the Government (which supports Commil in this case) argue that *Global-Tech* should be read as holding that only knowledge of the patent is required for induced infringement. That ... would contravene *Global-Tech*'s explicit holding that liability for induced infringement can only attach if the defendant knew of the patent and knew as well that "the induced acts constitute patent infringement." 131 S. Ct. at 2068.

... After noting the language of § 271(b) and the case law prior to passage of the Patent Act did not resolve the question, the *Global-Tech* Court turned to *Aro II*, a case about contributory infringement. The *Global-Tech* Court deemed that rules concerning contributory infringement were relevant to induced infringement, because the mental state imposed in each instance is similar. ...

*Aro II* concluded that to be liable for contributory infringement, a defendant must know the acts were infringing. 377 U.S. at 488. In *Global-Tech*, the Court said this reasoning was applicable, explaining as follows:

Based on this premise, it follows that the same knowledge is needed for induced infringement under § 271(b). As noted, the two provisions have a common origin in the pre-1952 understanding of contributory infringement, and the language of the two provisions creates the same difficult interpretive choice. It would thus be strange to hold that knowledge of the relevant patent is needed under § 271(c) but not under § 271(b).

Accordingly, we now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement. 131 S. Ct. at 2068.

In support of Commil, the Government argues against the clear language of *Global-Tech*. According to the Government, all *Global-Tech* requires is knowledge of the patent ... . It was not only knowledge of the existence of SEB's patent that led the Court to affirm the liability finding but also it was the fact that Pentalpha copied
“all but the cosmetic features of SEB’s fryer,” demonstrating Pentalpha knew it would be causing customers to infringe SEB’s patent. *Id.* at 2071.

Accepting the Government and Commil’s argument would require this Court to depart from its prior holding. And the *Global-Tech* rationale is sound. Qualifying or limiting its holding, as the Government and Commil seek to do, would lead to the conclusion, both in inducement and contributory infringement cases, that a person, or entity, could be liable even though he did not know the acts were infringing. In other words, even if the defendant reads the patent’s claims differently from the plaintiff, and that reading is reasonable, he would still be liable because he knew the acts might infringe. *Global-Tech* requires more. It requires proof the defendant knew the acts were infringing. And the Court’s opinion was clear in rejecting any lesser mental state as the standard.

**B**

The question the Court confronts today concerns whether a defendant’s belief regarding patent validity is a defense to a claim of induced infringement. It is not. The scienter element for induced infringement concerns infringement; that is a different issue than validity. Section 271(b) requires that the defendant “actively induce[d] infringement.” That language requires intent to “bring about the desired result,” which is infringement. 131 S. Ct. at 2065. And because infringement and validity are separate issues under the Act, belief regarding validity cannot negate the scienter required under § 271(b).

When infringement is the issue, the validity of the patent is not the question to be confronted. In *Cardinal Chemical Co. v. Morton Int’l, Inc.*, 508 U.S. 83 (1993), the Court explained, “A party seeking a declaratory judgment of invalidity presents a claim independent of the patentee’s charge of infringement.” *Id.* at 96. It further held noninfringement and invalidity were “alternative grounds” for dismissing the suit. *Id.* at 98. And in *Deposit Guaranty Nat. Bank v. Roper*, 445 U. S. 326, 334 (1980), the Court explained that an accused infringer “may prevail either by successfully attacking the validity of the patent or by successfully defending the charge of infringement.” These explanations are in accord with the long-accepted truth—perhaps the axiom—that infringement and invalidity are separate matters under patent law.

Indeed, the issues of infringement and validity appear in separate parts of the Patent Act. Part III of the Act deals with “Patents and Protection of Patent Rights,” including the right to be free from infringement. §§ 251-329. Part II, entitled “Patentability of Inventions and Grants of Patents,” defines what constitutes a valid patent. §§ 100-212. Further, noninfringement and invalidity are listed as two separate defenses, see §§ 282(b)(1), (2), and defendants are free to raise either or both of them. Were this Court to interpret § 271(b) as permitting a defense of belief in invalidity, it would conflate the issues of infringement and validity.

Allowing this new defense would also undermine a presumption that is a “common core of thought and truth” reflected in this Court’s precedents for a century. *Radio Corp. of America v. Radio Eng’g Labs.*, 293 U.S. 1, 8 (1934). Under the Patent Act, and the case law before its passage, a patent is “presumed valid.” § 282(a). That presumption takes away any need for a plaintiff to prove his patent is
valid to bring a claim. But if belief in invalidity were a defense to induced infringement, the force of that presumption would be lessened to a drastic degree, for a defendant could prevail if he proved he reasonably believed the patent was invalid. That would circumvent the high bar Congress is presumed to have chosen: the clear and convincing standard. See Microsoft Corp. v. i4i Ltd., 131 S. Ct. 2238, 2242 (2011). Defendants must meet that standard to rebut the presumption of validity.

To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics. See M. Swift & Sons, Inc. v. W.H. Coe Mfg., 102 F. 2d 391, 396 (1st Cir. 1939). But the questions courts must address when interpreting and implementing the statutory framework require a determination of the procedures and sequences that the parties must follow to prove the act of wrongful inducement and any related issues of patent validity. … To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed. But the allocation of the burden to persuade on these questions, and the timing for the presentations of the relevant arguments, are concerns of central relevance to the orderly administration of the patent system.

Invalidity is an affirmative defense that “can preclude enforcement of a patent against otherwise infringing conduct.” 6A Chisum on Patents § 19.01, at 19-5 (2015). An accused infringer can, of course, attempt to prove that the patent in suit is invalid; if the patent is indeed invalid, and shown to be so under proper procedures, there is no liability. That is because invalidity is not a defense to infringement, it is a defense to liability. And because of that fact, a belief as to invalidity cannot negate the scienter required for induced infringement.

There are also practical reasons not to create a defense based on a good-faith belief in invalidity. First and foremost, accused inducers who believe a patent is invalid have various proper ways to obtain a ruling to that effect. They can file a declaratory judgment action asking a federal court to declare the patent invalid. See MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 137 (2007). They can seek inter partes review at the Patent Trial & Appeal Board and receive a decision as to validity within 12 to 18 months. See § 316. Or they can, as Cisco did here, seek ex parte reexamination of the patent by the [PTO]. § 302. And, of course, any accused infringer who believes the patent in suit is invalid may raise the affirmative defense of invalidity. § 282(b)(2). If the defendant is successful, he will be immune from liability.

Creating a defense of belief in invalidity, furthermore, would have negative consequences. It can render litigation more burdensome for everyone involved. Every accused inducer would have an incentive to put forth a theory of invalidity and could likely come up with myriad arguments. And since “it is often more difficult to determine whether a patent is valid than whether it has been infringed,” Cardinal, 508 U.S. at 99, accused inducers would likely find it easier to prevail on a defense regarding the belief of invalidity than noninfringement. In addition the need to respond to the defense will increase discovery costs and multiply the issues the jury
must resolve. Indeed, the jury would be put to the difficult task of separating the defendant’s belief regarding validity from the actual issue of validity.

As a final note, “[o]ur law is *** no stranger to the possibility that an act may be ‘intentional’ for purposes of civil liability, even if the actor lacked actual knowledge that her conduct violated the law.” Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L.P.A., 559 U.S. 573, 582-583 (2010). Tortious interference with a contract provides an apt example. While the invalidity of a contract is a defense to tortious interference, belief in validity is irrelevant. Restatement (Second) of Torts § 766, Comment i (1979). In a similar way, a trespass “can be committed despite the actor’s mistaken belief that she has a legal right to enter the property.” Jerman, 559 U.S. at 583 (citing Restatement (Second) of Torts § 164, and Comment e (1963-1964)). And of course, “[t]he general rule that ignorance of the law or a mistake of law is no defense to criminal prosecution is deeply rooted in the American legal system.” Cheek v. United States, 498 U.S. 192, 199 (1991). In the usual case, “I thought it was legal” is no defense. That concept mirrors this Court’s holding that belief in invalidity will not negate the scienter required under § 271(b).

III

The Court is well aware that an “industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.” eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring). Some companies may use patents as a sword to go after defendants for money, even when their claims are frivolous. This tactic is often pursued through demand letters, which “may be sent very broadly and without prior investigation, may assert vague claims of infringement, and may be designed to obtain payments that are based more on the costs of defending litigation than on the merit of the patent claims.” L. Greisman, Prepared Statement of the Federal Trade Commission on Discussion Draft of Patent Demand Letter Legislation before the Subcommittee on Commerce, Manufacturing, & Trade of the House Committee on Energy & Commerce 2 (2014). This behavior can impose a “harmful tax on innovation.” Id.

No issue of frivolity has been raised by the parties in this case, nor does it arise on the facts presented to this Court. Nonetheless, it is still necessary and proper to stress that district courts have the authority and responsibility to ensure frivolous cases are dissuaded. If frivolous cases are filed in federal court, it is within the power of the court to sanction attorneys for bringing such suits. Fed. Rule Civ. Proc. 11. It is also within the district court’s discretion to award attorney’s fees to prevailing parties in “exceptional cases.” 35 U.S.C. § 285. These safeguards, combined with the avenues that accused inducers have to obtain rulings on the validity of patents, militate in favor of maintaining the separation expressed throughout the Patent Act between infringement and validity. This dichotomy means that belief in invalidity is no defense to a claim of induced infringement.

…
Scalia, J., dissenting (for himself and Chief Justice Roberts):

I agree with the Court’s rejection of the main argument advanced by Commil and the United States, that induced infringement under 35 U.S.C. § 271(b) does not “require[e] knowledge of the infringing nature of the induced acts.” Brief for United States as Amicus Curiae 9. I disagree, however, with the Court’s holding that good-faith belief in a patent’s invalidity is not a defense to induced infringement.

Infringing a patent means invading a patentee’s exclusive right to practice his claimed invention. Crown Die & Tool Co. v. Nye Tool & Machine Works, 261 U.S. 24, 40 (1923) (quoting 3 W. Robinson, Law of Patents § 937, at 122-23 (1890)). Only valid patents confer this right to exclusivity—invalid patents do not. It follows, as night the day, that only valid patents can be infringed. To talk of infringing an invalid patent is to talk nonsense.

Induced infringement, we have said, “requires knowledge that the induced acts constitute patent infringement.” Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011). Because only valid patents can be infringed, anyone with a good-faith belief in a patent’s invalidity necessarily believes the patent cannot be infringed. And it is impossible for anyone who believes that a patent cannot be infringed to induce actions that he knows will infringe it. A good-faith belief that a patent is invalid is therefore a defense to induced infringement of that patent.

The Court makes four arguments in support of the contrary position. None seems to me persuasive. First, it notes that the Patent Act treats infringement and validity as distinct issues. That is true. It is also irrelevant. Saying that infringement cannot exist without a valid patent does not “conflate the issues of infringement and validity,” any more than saying that water cannot exist without oxygen “conflates” water and oxygen. Recognizing that infringement requires validity is entirely consistent with the “long-accepted truth *** that infringement and invalidity are separate matters under patent law.”

The Court next insists that permitting the defense at issue would undermine the statutory presumption of validity. It would do no such thing. By reason of the statutory presumption of validity, § 282(a), patents can be held invalid only by clear and convincing evidence. This presumption is not weakened by treating a good-faith belief in invalidity as a defense to induced infringement. An alleged inducer who succeeds in this defense does not thereby call a patent’s validity into question. He merely avoids liability for a third party’s infringement of a valid patent, in no way undermining that patent’s presumed validity.

Next, the Court says that “invalidity is not a defense to infringement, it is a defense to liability.” That is an assertion, not an argument. Again, to infringe a patent is to invade the patentee’s right of exclusivity. An invalid patent confers no such right. How is it possible to interfere with rights that do not exist? The Court has no answer.

That brings me to the Court’s weakest argument: that there are “practical reasons not to create a defense based on a good-faith belief in invalidity.” (Emphasis added). Ours is not a common-law court. Eric R. Co. v. Tompkins, 304 U.S. 64, 78
(1938). We do not, or at least should not, create defenses to statutory liability—and that is not what this dissent purports to do. Our task is to interpret the Patent Act, and to decide whether it makes a good-faith belief in a patent’s invalidity a defense to induced infringement. Since, as we said in Global-Tech, the Act makes knowledge of infringement a requirement for induced-infringement liability; and since there can be no infringement (and hence no knowledge of infringement) of an invalid patent; good-faith belief in invalidity is a defense. I may add, however, that if the desirability of the rule we adopt were a proper consideration, it is by no means clear that the Court’s holding, which increases the in terrorem power of patent trolls, is preferable. The Court seemingly acknowledges that consequence in Part III of its opinion.

For the foregoing reasons, I respectfully dissent.

Patent Territoriality & Transborder Business

Deepsouth Packing Co. v. Laitram Corp.

406 U.S. 518 (1972)

White, Justice:

... Petitioner and respondent both hold patents on machines that de vein shrimp more cheaply and efficiently than competing machinery or hand labor can do the job. Extensive litigation below has established that respondent, the Laitram Corp., has the superior claim and that the distribution and use of petitioner Deepsouth’s machinery in this country should be enjoined to prevent infringement of Laitram’s patents. We granted certiorar to consider a related question: Is Deepsouth, barred from the American market by Laitram’s patents, also foreclosed by the patent laws from exporting its deveiners, in less than fully assembled form, for use abroad?

I

A rudimentary understanding of the patents in dispute is a prerequisite to comprehending the legal issue presented. The District Court determined that the Laitram Corp. held two valid patents for machinery used in the process of deveining shrimp. One, granted in 1954, accorded Laitram rights over a “slitter” which exposed the veins of shrimp by using water pressure and gravity to force the shrimp down an inclined trough studded with razor blades. As the shrimp descend through the trough their backs are slit by the blades or other knife-like objects arranged in a zig-zag pattern. The second patent, granted in 1958, covers a “tumbler,” “a device to mechanically remove substantially all veins from shrimp whose backs have previously been slit” by the machines described in the 1954 patent. This invention uses streams of water to carry slit shrimp into and then out of a revolving drum fabricated from commercial sheet metal. As shrimp pass through the drum the hooked “lips”

2 This patent expired shortly before argument in this court and is therefore not relevant to Laitram’s claim for injunctive relief. It is described, however, because Laitram claims damages for Deepsouth’s asserted past exportation of the parts of this machine.
of the punched metal, “projecting at an acute angle from the supporting member and having a smooth rounded free edge for engaging beneath the vein of a shrimp and for wedging the vein between the lip and the supporting member,” engage the veins and remove them.

Both the slitter and the tumbler are combination patents; that is

[n]one of the parts referred to are new, and none are claimed as new; nor is any portion of the combination less than the whole claimed as new, or stated to produce any given result. The end in view is proposed to be accomplished by the union of all, arranged and combined together in the manner described. And this combination, composed of all the parts mentioned in the specification, and arranged with reference to each other, and to other parts of the [machine] in the manner therein described, is stated to be the improvement, and is the thing patented.


... As is usual in combination patents, none of the elements in either of these patents were themselves patentable at the time of the patent, nor are they now. ... The patents were warranted not by the novelty of their elements but by the novelty of the combination they represented. Invention was recognized because Laitram’s assignors combined ordinary elements in an extraordinary way—a novel union of old means was designed to achieve new ends. ...

II

The lower court’s decision that Laitram held valid combination patents entitled the corporation to the privileges bestowed by 35 U.S.C. § 154, the keystone provision of the patent code. ... [F]rom the [issue] date of the patent, Laitram had “the right to exclude others from making, using, or selling the invention throughout the United States ... .” The § 154 right in turn provides the basis for affording the patentee an injunction against direct, induced, and contributory infringement, 35 U.S.C. § 283, or an award of damages when such infringement has already occurred, 35 U.S.C. § 284. Infringement is defined by 35 U.S.C. § 271 in terms that follow those of § 154 ... .

As a result of these provisions the judgment of Laitram’s patent superiority forecloses Deepsouth and its customers from any future use (other than a use approved by Laitram or occurring after the Laitram patent has expired) of its deveiners “throughout the United States.” The patent provisions taken in conjunction with the judgment below also entitle Laitram to the injunction it has received prohibiting Deepsouth from continuing to “make” or, once made, to “sell” deveiners “throughout the United States.” Further, Laitram may recover damages for any past unauthorized use, sale, or making “throughout the United States.” This much is not disputed.

But Deepsouth argues that it is not liable for every type of past sale and that a portion of its future business is salvageable. Section 154 and related provisions obviously are intended to grant a patentee a monopoly only over the United States market; they are not intended to grant a patentee the bonus of a favored position as a flagship company free of American competition in international commerce.
Deepsouth, itself barred from using its deveining machines, or from inducing others to use them “throughout the United States,” barred also from making and selling the machines in the United States, seeks to make the parts of deveining machines, to sell them to foreign buyers, and to have the buyers assemble the parts and use the machines abroad. Accordingly, Deepsouth seeks judicial approval, expressed through a modification or interpretation of the injunction against it, for continuing its practice of shipping deveining equipment to foreign customers in three separate boxes, each containing only parts of the 1¾-ton machines, yet the whole assemblable in less than one hour. The company contends that by this means both the “making” and the “use” of the machines occur abroad and Laitram’s lawful monopoly over the making and use of the machines throughout the United States is not infringed.

Laitram counters that this course of conduct is based upon a hypertechnical reading of the patent code that, if tolerated, will deprive it of its right to the fruits of the inventive genius of its assignors. “The right to make can scarcely be made plainer by definition.” Bauer v. O’Donnell, 229 U. S. 1, 10 (1913). Deepsouth in all respects save final assembly of the parts “makes” the invention. It does so with the intent of having the foreign user effect the combination without Laitram’s permission. Deepsouth sells these components as though they were the machines themselves; the act of assembly is regarded, indeed advertised, as of no importance.

The District Court, faced with this dispute, noted that three prior circuit courts had considered the meaning of “making” in this context and that all three had resolved the question favorably to Deepsouth’s position. See Hewitt-Robins, Inc. v. Link-Belt Co., 371 F.2d 225 (7th Cir. 1966); Cold Metal Process Co. v. United Engineering & Foundry Co., 235 F.2d 224 (3rd Cir. 1956); and Radio Corp. of America v. Andrea, 79 F.2d 626 (2d Cir. 1935). The District Court held that its injunction should not be read as prohibiting export of the elements of a combination patent even when those elements could and predictably would be combined to form the whole. “It may be urged that *** [this] result is not logical. *** But it is founded on twin notions that underlie the patent laws. One is that a combination patent protects only the combination. The other is that monopolies—even those conferred by patents—are not viewed with favor. These are logic enough.”

The Court of Appeals for the Fifth Circuit reversed, thus departing from the established rules of the Second, Third, and Seventh Circuits. In the Fifth Circuit panel’s opinion, those courts that previously considered the question “worked themselves into *** a conceptual box” by adopting “an artificial, technical construction” of the patent laws, a construction, moreover, which in the opinion of the panel, 5

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5 Deepsouth is entirely straightforward in indicating that its course of conduct is motivated by a desire to avoid patent infringement. Its president wrote a Brazilian customer: “We are handicapped by a decision against us in the United States. This was a very technical decision and we can manufacture the entire machine without any complication in the United States, with the exception that there are two parts that must not be assembled in the United States, but assembled after the machine arrives in Brazil.”
“[subverted] the Constitutional scheme of promoting ‘the Progress of Science and useful Arts’” by allowing an intrusion on a patentee’s rights.

III

We disagree with the Court of Appeals for the Fifth Circuit. Under the common law the inventor had no right to exclude others from making and using his invention. If Laitram has a right to suppress Deepsouth’s export trade it must be derived from its patent grant, and thus from the patent statute. We find that 35 U.S.C. § 271, the provision of the patent laws on which Laitram relies, does not support its claim.

Certainly if Deepsouth’s conduct were intended to lead to use of patented deveiners inside the United States its production and sales activity would be subject to injunction as an induced or contributory infringement. But it is established that there can be no contributory infringement without the fact or intention of a direct infringement. “In a word, if there is no [direct] infringement of a patent there can be no contributory infringer.” Mercoid Corp. v. Mid-Continent Co., 320 U. S. 661, 677 (1944) (Frankfurter, J., dissenting on other grounds). Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U. S. 336, 341-342 (1961), succinctly articulates the law:

It is plain that § 271 (c)—a part of the Patent Code enacted in 1952—made no change in the fundamental precept that there can be no contributory infringement in the absence of a direct infringement. That section defines contributory infringement in terms of direct infringement—namely the sale of a component of a patented combination or machine for use “in an infringement of such patent.”

The statute makes it clear that it is not an infringement to make or use a patented product outside of the United States. 35 U.S.C. § 271. See also Dowagiac Mfg. Co. v. Minnesota Moline Plow Co., 235 U. S. 641, 650 (1915); Brown v. Duchesne, 60 U. S. (19 How.) 183 (1857). Thus, in order to secure the injunction it seeks, Laitram must show a § 271(a) direct infringement by Deepsouth in the United States—that is, that Deepsouth “makes,” “uses,” or “sells” the patented product within the bounds of this country.

Laitram does not suggest that Deepsouth “uses” the machines. Its argument that Deepsouth sells the machines—based primarily on Deepsouth’s sales rhetoric and related indicia such as price—cannot carry the day unless it can be shown that Deepsouth is selling the “patented invention.” The sales question thus resolves itself

8 “But the right of property which a patentee has in his invention, and his right to its exclusive use, is derived altogether from these statutory provisions; and this court (has) always held that an inventor has no right of property in his invention, upon which he can maintain a suit, unless he obtains a patent for it, according to the acts of Congress; and that his rights are to be regulated and measured by these laws, and cannot go beyond them.” Brown v. Duchesne, 60 U. S. (19 How.) 183, 195 (1857).

9 Deepsouth sold the less than completely assembled machine for the same price as it had sold fully assembled machines. Its advertisements, correspondence, and invoices frequently referred to a “machine,” rather than to a kit or unassembled parts.
into the question of manufacture: did Deepsouth “make” (and then sell) something cognizable under the patent law as the patented invention, or did it “make” (and then sell) something that fell short of infringement?

The Court of Appeals, believing that the word “makes” should be accorded “a construction in keeping with the ordinary meaning of that term,” held against Deepsouth on the theory that “makes” “means what it ordinarily connotes—the substantial manufacture of the constituent parts of the machine.” Passing the question of whether this definition more closely corresponds to the ordinary meaning of the term than that offered by Judge Swan in Andrea 35 years earlier (something is made when it reaches the state of final operable assembly), we find the Fifth Circuit’s definition unacceptable because it collides head on with a line of decisions so firmly embedded in our patent law as to be unassailable absent a congressional recasting of the statute.

We cannot endorse the view that the “substantial manufacture of the constituent parts of [a] machine” constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts. “For as we pointed out in Mercoid v. Mid-Continent Investment Co., 320 U.S. 661, 676, a patent on a combination is a patent on the assembled or functioning whole, not on the separate parts.” Mercoid Corp. v. Minneapolis-Honeywell Regulator Co., 320 U.S. 680, 684 (1944). See also Leeds & Catlin Co. v. Victor Talking Machine Co., 213 U.S. 301, 318 (1909) (“A combination is a union of elements, which may be partly old and partly new, or wholly old or wholly new. But whether new or old, the combination is a means—an invention—distinct from them.”); id. at 320 (“[O]ne element is not the combination. Indeed, all of the elements are not. To be that—to be identical with the invention of the combination—they must be united by the same operative law.”). In sum,

[i]f anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant.


It was this basic tenet of the patent system that led Judge Swan to hold in the leading case, Radio Corp. of America v. Andrea, 79 F.2d 626 (2d Cir. 1935), that unassembled export of the elements of an invention did not infringe the patent.

[The] relationship is the essence of the patent.

*** No wrong is done the patentee until the combination is formed. His monopoly does not cover the manufacture or sale of separate elements capable of being, but never actually, associated to form the invention. Only when such association is made is there a direct infringement of his monopoly, and not even then if it is done outside the territory for which the monopoly was granted.

Id. at 628. See also Cold Metal Process Co. v. United Engineering & Foundry Co., 235 F.2d at 230 (“We are in full accord with the rule thus laid down in the Andrea case and we think that the master and the district court were right in applying it here.”); Hewitt-Robins, Inc. v. Link Belt Co., 371 F.2d at 229 (to the same effect).
We reaffirm this conclusion today.

IV

It is said that this conclusion is derived from too narrow and technical an interpretation of the statute, and that this Court should focus on the constitutional mandate

[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ***

Art. I, § 8, and construe the statute in a manner that would, allegedly, better reflect the policy of the Framers.

We cannot accept this argument. The direction of Art. I is that Congress shall have the power to promote the progress of science and the useful arts. When, as here, the Constitution is permissive, the sign of how far Congress has chosen to go can come only from Congress. We are here construing the provisions of a statute passed in 1952. The prevailing law in this and other courts as to what is necessary to show a patentable invention when a combination of old elements is claimed was clearly evident from the cases when the Act was passed; and at that time [the decision in] Andrea, representing a specific application of the law of infringement with respect to the export of elements of a combination patent, was 17 years old. When Congress drafted § 271, it gave no indication that it desired to change either the law of combination patents as relevant here or the ruling of Andrea. Nor has it on any more recent occasion indicated that it wanted the patent privilege to run farther than it was understood to run for 35 years prior to the action of the Court of Appeals for the Fifth Circuit.

Moreover, we must consider petitioner’s claim in light of this Nation’s historical antipathy to monopoly and of repeated congressional efforts to preserve and foster competition. As this Court recently said without dissent:

[I]n rewarding useful invention, the ‘rights and welfare of the community must be fairly dealt with and effectually guarded.’ Kendall v. Winsor, 62 U.S. (21 How.) 322, 329 (1859). To that end the prerequisites to obtaining a patent are strictly observed, and when the patent has issued the limitations on its exercise are equally strictly enforced.


It follows that we should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought. No such signal legitimizes respondent’s position in this litigation.

In conclusion, we note that what is at stake here is the right of American companies to compete with an American patent holder in foreign markets. Our patent system makes no claim to extraterritorial effect; “these acts of Congress do not, and were not intended to, operate beyond the limits of the United States,” Brown v.
Miller’s Patent Cases

Duchesne, 60 U.S. (19 How.) at 195, and we correspondingly reject the claims of others to such control over our markets. To the degree that the inventor needs protection in markets other than those of this country, the wording of 35 U.S.C. §§ 154 and 271 reveals a congressional intent to have him seek it abroad through patents secured in countries where his goods are being used. Respondent holds foreign patents; it does not adequately explain why it does not avail itself of them.

In sum: the case and statutory law resolves this case against the respondent. When so many courts have so often held what appears so evident—a combination patent can be infringed only by combination—we are not prepared to break the mold and begin anew. And were the matter not so resolved, we would still insist on a clear congressional indication of intent to extend the patent privilege before we could recognize the monopoly here claimed. Such an indication is lacking. Accordingly, the judgment of the Court of Appeals for the Fifth Circuit is reversed and the case is remanded for proceedings consistent with this opinion.

Blackmun, Justice, with whom Chief Justice Burger and Justices Powell and Rehnquist join, dissenting:

Because our grant of certiorari was limited, the customarily presented issues of patent validity and infringement are not before us in this case. I necessarily accept, therefore, the conclusion that the Laitram patents are valid and that the Deepsouth deveining machine, when manufactured and assembled in the United States, is an infringement. The Court so concedes. The Court, however, denies Laitram patent law protection against Deepsouth’s manufacture and assembly when the mere assembly is effected abroad. It does so on the theory that there then is no “making” of the patented invention in the United States even though every part is made here and Deepsouth ships all the parts in response to an order from abroad.

With all respect, this seems to me to be too narrow a reading of 35 U.S.C. §§ 154 and 271(a). In addition, the result is unduly to reward the artful competitor who uses another’s invention in its entirety and who seeks to profit thereby. Deepsouth may be admissive and candid or, as the Court describes it, “straightforward” in its “sales rhetoric,” but for me that rhetoric reveals the very iniquitous and evasive nature of Deepsouth’s operations. I do not see how one can escape the conclusion that the Deepsouth machine was made in the United States, within the meaning of the protective language of §§ 154 and 271(a). …

…

National Steel Car v. Canadian Pacific Railway

357 F.3d 1319 (Fed. Cir. 2004)

Clevenger, Judge:

Plaintiff-Appellee National Steel Car sued Defendants-Appellants Canadian Pacific Railway [and others] in the Eastern District of Pennsylvania for infringement of U.S. Patent No. 4,951,575. NSC moved for a preliminary injunction, and the district court granted NSC’s motion, holding inter alia that NSC had demonstrated a likelihood of success on the merits [and] that CPR’s defense to infringement under
35 U.S.C. § 272 lacked substantial merit ... . After careful review of the district court’s opinion, the record, and the arguments advanced by the parties, ... we reverse the district court’s preliminary injunction.

I

The ’575 patent, assigned to National Steel Car, a manufacturer of railway cars, addresses a particular type of railway car used to haul lumber: a depressed center-beam flat car. Figure 1 of the ’575 patent shows a longitudinal section through one side of the car and is reproduced below.

![Diagram of the car](image)

The car described in the ’575 patent is a “center-beam” car because the primary structure of the car is a truss-like beam element that runs the length of the center of the car between the wheel assemblies, or “end truck assemblies,” in the front and back of the car. Center-beam cars are an industry standard for hauling lumber, which is piled onto a floor that extends laterally to each side of the car from the bottom of the center beam and then secured to the center beam. Canadian Pacific currently operates a fleet of center-beam flat cars.

The car described in the ’575 patent is a “depressed,” or “drop-deck,” car because the portion of the floor between the end truck assemblies is lowered relative to the height of the floor over the end truck assemblies. The drop-deck center-beam flat car has two advantages over the non-drop-deck version. First, it can carry a volumetrically larger load. Given the relatively low density of wood, ordinary center-beam cars reach volume capacity before they reach weight capacity, leaving each car inefficiently under-loaded in terms of weight. Second, the dropping of the deck lowers the car’s center of the gravity, permitting safer loading, transit, and unloading because a higher center of gravity renders the car more vulnerable to tipping.

II

Canadian Pacific is a Canadian railroad company that owns rail lines in Canada and in the United States and operates trains on these lines. On May 21, 2002, CPR issued a Request for Quote for a new fleet of depressed center-beam flat cars. Although NSC was among the three companies that submitted bids, CPR awarded a contract for 525 cars to Greenbrier, a United States company with a Trenton-Works production facility in Canada at which the cars were to be produced. The contract was based on Greenbrier’s GBRX 20003 model of a depressed center-beam flat car. The contract was for a total of over $21 million and included a broad provision under which Greenbrier agreed to defend patent-infringement suits brought against
CPR, to indemnify CPR against all damages in any such suit, and to provide a suitable remedy should use of the cars be enjoined.

CPR intends to use the GBRX 20003 depressed center-beam flat cars in the same way that it uses its current fleet of 2,900 lumber-carrying center-beam flat cars. Ninety percent of CPR’s lumber shipments travel from Canada to the United States; the remaining ten percent are performed entirely within Canada. Because there is no market need for American lumber to be shipped into Canada, CPR center-beam flat cars return to Canada empty 99.2 percent of the time. Measured either on the basis of days or track mileage traveled, a center-beam flat car is in the United States approximately 56 to 57 percent of the time.

To service destinations in the United States, CPR engines pull the CPR cars as far as CPR-owned track extends into the United States. If the destination lies beyond the end of the CPR track, the CPR cars are switched at an interchange point, such as Chicago, Illinois, to trains powered by locomotives owned by United States railroads. At an interchange point, CPR cars from the same incoming train may end up on different trains heading to different United States destinations.

III

During the course of the bidding process on Canadian Pacific’s fleet of depressed center-beam flat cars, National Steel Car apprised CPR of the existence of the ’575 patent and indicated that it was prepared to protect its patent rights. Less than a month after CPR informed NSC that its bid had not been accepted, NSC filed the complaint initiating the instant suit, alleging infringement of … the ’575 patent based on CPR's intended use of the drop-deck center-beam flat cars in the United States. NSC moved for a preliminary injunction against CPR, and after an expedited discovery period and an evidentiary hearing, the district court granted the motion. The district court’s preliminary injunction enjoins CPR “from making, using, offering to sell, or importing the GBRX 20003 depressed center beam flat car in the United States.”

In the preliminary injunction proceedings before the district court, CPR conceded that limitations in the claims of the ’575 patent read on the GBRX 20003. The questions considered by the district court in its analysis of NSC’s likelihood of success on the merits, therefore, focused on CPR’s defenses to patent infringement. The district court held that neither of the two defenses raised by CPR had substantial merit. CPR first claimed that 35 U.S.C. § 272 defines CPR’s use of the accused cars as noninfringing. …

V

We first address Canadian Pacific’s defense to infringement under § 272. The statutory interpretation of § 272 presents an issue of law that we review without deference. See Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1564 (Fed. Cir. 1995).

Section 272, entitled “Temporary presence in the United States,” provides as follows:
The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

In gross, § 272 provides that the use of certain foreign-owned means of transit or transport entering into the jurisdiction of the United States “temporarily or accidentally” is not an infringing use provided a host of conditions are satisfied. CPR argues that its intended use of the GBRX 20003 drop-deck center-beam flat cars in the United States is within the scope of conduct detailed in § 272, and that its use of the cars therefore does not constitute infringement of the ’575 patent. The district court disagreed … .

Because we have never before had the opportunity to address the scope of § 272, we outline briefly the statute’s history and the interpretive resources at our disposal. …

A

Although § 272 was enacted as part of the 1952 revision of the patent laws, its legislative history is brief, noting only that § 272 was drafted to codify the Supreme Court’s holding in *Brown v. Duchesne*, 60 U.S. (19 How.) 183 (1856), and to satisfy the obligations of the United States under the Paris Convention for the Protection of Industrial Property (“Paris Convention”). See H.R. Rep. No. 82-1923 at 10 (1952) (“Section 272 is a new section in the law relating to infringement, but it is of relatively little importance and it follows a paragraph in a treaty to which the United States is a party.”); S. Rep. No. 82-1979 at 28 (1952) (“This section follows the requirement [in Article 5ter] of the International Convention for the Protection of Industrial Property, to which the United States is a party, and also codifies the holding of the Supreme Court [in Brown] that use of a patented invention on board a foreign ship does not infringe a patent.”).

In the middle of the nineteenth century, nearly a century before the enactment of § 272, the Supreme Court in *Brown* held that the owner of a patent on an invention related to the rigging of a sailing ship had no cause of action against the master of [the] French schooner [*Alcyon*] that voyaged between Boston and a colony of France and that embodied the invention. See 60 U.S. (19 How.) at 193. Given “that the improvement in question was placed on [the ship] in a foreign port *** and was authorized by the laws of the country to which she belonged,” the question presented was:

[W]hether any improvement in the construction or equipment of a foreign vessel, for which a patent has been obtained in the United States, can be used by such vessel within the jurisdiction of the United States, while she is temporarily there for the purposes of commerce, without the consent of the patentee.
Miller’s Patent Cases

*Id.* at 194. Eschewing a narrowly framed plain meaning analysis of the patent laws then on the books, the Court held that an interpretation of a patent right so broad as to label the French vessel’s use of the invention as an infringing use:

[W]ould confer on patentees not only the rights of property, but also political power, and enable them to embarrass the treaty-making power in its negotiations with foreign nations, and also to interfere with the legislation of Congress when exercising its constitutional power to regulate commerce.

*Id.* at 197. Thus, because the Court considered it unlikely that Congress would have intended to delegate such broad authority to patentees, the Court construed the statutory rights of a patentee not to extend to:

[T]he use of [a patented] improvement, in the construction, fitting out, or equipment of such vessel, while she is coming into or going out of a port of the United States *** provided it was placed upon her in a foreign port, and authorized by the laws of the country to which she belongs.

*Id.* at 198-99.

The holding in *Brown* thus circumscribes the rights of a U.S. patent holder vis-a-vis the use of a patented invention on foreign vessels present in the United States. However, other language in the opinion clearly demonstrates that the Court did not intend to place all conduct on such vessels outside the scope of a patentee’s rights:

If [the invention] had been manufactured on her deck while she was lying in the port of Boston, or if the captain had sold it there, he would undoubtedly have trespassed upon the rights of the plaintiff, and would have been justly answerable for the profit and advantage he thereby obtained.

*Id.* at 196. Only the use of a patented invention “in the construction, fitting out, or equipment of such vessel[s]” was held to constitute a noninfringing use. *Id.* at 198.

The relevant section of Article 5ter of the Paris Convention reads as follows:

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6 “The general words used in the clause of the patent laws granting the exclusive right to the patentee to use the improvement, taken by themselves, and literally construed, without regard to the object in view, would seem to sanction the claim of the plaintiff. But this mode of expounding a statute has never been adopted by any enlightened tribunal—because it is evident that in many cases it would defeat the object which the Legislature intended to accomplish.” *Brown*, 60 U.S. (19 How.) at 194.

7 Although the Court decided the case on the basis of statutory interpretation, it further questioned whether an individual’s ability to exercise patent rights in such a situation would amount to an impermissible delegation of Congress’ treaty power and its power to regulate international commerce, *id.* at 198, or whether Congress itself could constitutionally regulate international commerce through a statute passed under the auspices of the Patent and Copyright Clause, which granted a power that was “domestic in its character,” *id.* at 195.
In any country of the Union the following shall not be considered as infringements of the rights of a patentee:

***

2. the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft of land vehicles temporarily or accidentally enter the said country.8


There are only two cases in which federal courts have applied § 272. In Cali v. Japan Airlines, Inc., 380 F. Supp. 1120 (E.D.N.Y. 1974), aff’d, 535 F.2d 1240 (2d Cir. 1975), the Eastern District of New York held that the use of a patented invention in the jet engines of planes belonging to international air carriers during “their flights to and from the United States and their over-flights of the United States in the course of the regular prosecution of their scheduled air services” was within the scope of the noninfringing uses specified in § 272. Id. at 1122, 1124. In Hughes Aircraft Co. v. United States, 29 Fed. Cl. 197 (1993), the Court of Federal Claims held that spacecraft brought into the United States for launch into outer space prior to 19819 were outside the scope of § 272. Id. at 232 (“When a spacecraft is delivered to the United States for the purpose of allowing the United States to launch it, the spacecraft is the cargo that is brought here for an essential use, not a ‘vessel’ or ‘vehicle’ which enters the United States as a means of conveyance.”).

B

First, the district court held that the invention of the ’575 patent embodied in the GBRX 20003 was not used in a vehicle of a country other than the United States. According to the district court, the train, not the rail car, is the relevant vehicle to examine under § 272, and the nationality of the locomotive determines the nationality of the train. Therefore, because the accused rail cars will be used in the United States in trains powered by locomotives owned and operated by United States companies on the United States side of the exchange points, the district court held that CPR’s intended use of the GBRX 20003 was beyond the scope of § 272.

Although we recognize that in some instances there may be ambiguity between containers that are merely the cargo of a vessel or vehicle, and vessels or vehicles that are themselves aggregated and transported in a collective fashion for greater efficiency, we discern no such ambiguity here: Congress has defined “vehicle” with sufficient breadth to include an individual rail car. In 1 U.S.C. § 4, a provision of the Dictionary Act, Congress has provided that “[t]he word ‘vehicle’ includes every de-

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8 A separate provision in Article 5ter, excerpted from the quoted language, applies to “vessels.”

9 In 1981, Congress enacted 42 U.S.C. § 2457(k), which provides that “[a]ny object intended for launch, launched, or assembled in outer space shall be considered a vehicle for the purpose of § 272.”
scription of carriage or other artificial contrivance used, or capable of being used, as a means of transportation on land.” The ordinary meaning of “carriage,” in turn, is defined to encompass “means of conveyance,” “a wheeled vehicle for people,” or “a wheeled support carrying a burden,” such as “a gun carriage.” *Webster’s Third New International Dictionary* 343 (1993). This definition controls our interpretation of “vehicle” in § 272, cf. P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 54 (West 1954) (stating that the definition of “vehicle” provided in 1 U.S.C. § 4 would apply to § 272), and leads us to define a rail car individually—not only the train as a whole—as a vehicle within the meaning of § 272. We therefore conclude that a depressed center-beam flat car owned by CPR may be a foreign vehicle and therefore is not disqualified from the noninfringing status created by § 272 on this basis.

The next question presented is also a legal question involving statutory interpretation: When is a vehicle only “entering the United States temporarily” under § 272? The district court held that the accused rail car will not be “temporarily” present in the United States, as required by § 272, because it “will spend the majority of its time delivering lumber to United States destinations” and because CPR “will derive significant benefits from using the accused rail car in the United States.” The district court thus determined that the appropriate statutory metric by which to measure whether a vehicle is entering “temporarily” should be either the duration of the vehicle’s stay in the United States, in relation to the duration of its stay elsewhere, or the benefit of which the patent owner is deprived by virtue of the exception to patent rights created by § 272. We decline to adopt either metric, and instead define a vehicle entering the United States “temporarily” as a vehicle entering the United States for a limited period of time for the sole purpose of engaging in international commerce.

We begin by noting that the statutory language is ambiguous, rather than clear and unambiguous, insofar as it limits entries to those occurring “temporarily.” According to the word’s plain meaning, entering “temporarily” is entering either “for a brief period” or “during a limited time.” *Webster’s Third New International Dictionary* 2353 (1993). Not only, however, is the term “temporarily” ambiguous in the sense that it can be understood in different manners, neither of its meanings, alone, leads to a permissible, self-sufficient interpretation. On the one hand, the concept of entry for a “brief period” does not provide sufficient content by which to draw a reasonable or steady line: *Brief* is only a relative concept and must be measured in relation to something, but the plain statutory language, considered in isolation, does not provide sufficient context to determine the appropriate meaning of brief. In other words, “brief” is itself indeterminate. On the other hand, the idea of an entering for a “limited time” provides a rule that is determinable, but that seems to lead to absurdly broad results if applied literally without any further qualifications. Limited means nothing more than “restricted in *** duration.” *Id.* at 1312. Entry is literally limited provided only that it is not permanent. An interpretation of § 272 that only required a limited entry in this literal sense—that only required a vehicle to exit the United States at some point before the end of its useful life—and nothing
more would create a loophole in a patentee’s rights too large to be a rational interpretation of Congress’ intent. See Pitsker v. Office of Pers. Mgmt., 234 F.3d 1378, 1383 (Fed. Cir. 2000) (invoking “the canon of statutory construction that an interpretation that causes absurd results is to be avoided if at all possible”) (citing Hagar Co. v. Helvering, 308 U.S. 389, 394 (1940)).

Confronted with an ambiguous statute, we turn to the legislative history to discern Congress’ intent in defining “temporarily,” which in turn directs us to Brown and the Paris Convention. In addition to the requirement that entry be for only a limited period of time, both of these sources suggest that “temporarily” should be interpreted in light of a vehicle’s purpose to participate in international commerce at the time of entry—namely, a purpose to enter the United States, engage in international commerce, and then depart.

Brown emphasized that a construction of the patent laws under which a United States patentee could bring infringement suits against the use of an invention on vessels such as the French schooner at issue was undesirable because it “would *** seriously embarrass the commerce of the country with foreign nations.” Brown, 60 U.S. (19 How.) at 197. The Court also noted that the vessel’s interference with the rights of the patentee was minimal precisely because the schooner entered the United States only to use the port of Boston, and departed from the jurisdiction of the United States after its commercial transaction was completed. See id. at 196 (“[T]he only use made of [the invention], which can be supposed to interfere with the rights of the plaintiff, was in navigating the vessel into and out of the harbor, when she arrived or was about to depart, and while she was within the jurisdiction of the United States.”). In sum, the Court held that the use of a patented invention in a vessel within the jurisdiction of the United States that was limited to the bare essentials of the contact with the United States required to engage in international commerce was beyond the scope of the patentee’s exclusive rights.

Although the statutory interpretation in Brown involved a unilateral act on the part of the United States, both Article 5ter of the Paris Convention and § 272 demonstrate the centrality of international commerce in the statutory scheme through their provisions requiring reciprocal treatment for means of transport owned by United States companies that are “temporarily” present in foreign countries.

Both Brown and Article 5ter of the Paris Convention demonstrate a concern to leave the channels of international commerce, or more accurately the vessels and vehicles that pass through these channels, free from the excessive burdens that would result if such vessels or vehicles had to conform to the patent laws of all nations that the vessel or vehicle visited during its lifetime. Different inventions are likely to be patented in different countries, and the same invention may be owned by different parties in different countries. In § 272, Congress intended to join an international movement to place foreign-owned means of international transport beyond the reach of domestic patentees’ exclusive rights because the cost of complying with multiple, inconsistent rights of exclusion provided by the patent regimes of a large number of countries would likely place an excessive drag on international commerce.
Although their opinions are not binding on us, it is interesting to note that other courts considering similar issues have suggested the very definition of “temporarily” that we adopt today. For example, the court in Cali concluded that entering the United States “temporarily” should be defined in relation to the vehicle’s—or in the case of Cali, the aircraft’s—involvement in international, as opposed to domestic, commerce. In Cali, the court noted that “it is undeniable[] that *** defendants are major transoceanic carriers and that their passenger and freight services to the United States and over the United States are regular, of very considerable extent, long continued, and supported by ground service, marketing facilities, etc.” 380 F. Supp. at 1122. Nonetheless, the court held that § 272 provided a full defense to a patent infringement suit for the use of the patented invention because “temporarily” was defined in relation to the “international trade” that § 272 was intended to protect, not in relation to the duration of the entry:

It is difficult to see any other purpose in § 272 and Article 5*er than to meet the needs and realities of international trade and navigation. “Temporarily,” then, could not sensibly mean any less than entering for the purpose of completing a voyage, turning about, and continuing or commencing a new voyage. The distinction would be between a Caravelle, manufactured in France and powered with such an [allegedly infringing] engine, delivered here for use by an airline in this country for domestic traffic, even though manufactured and sold in France, and a foreign aircraft arriving here on an international flight only to unload, turn about, reload and depart.

Id. at 1126.

In conclusion, we hold that the definition of entering “temporarily,” as the word is used in § 272, is entering for a period of time of finite duration with the sole purpose of engaging in international commerce. In light of our interpretation of § 272, we reject both prongs of the district court’s reasoning explaining why the accused rail cars would not be entering the United States “temporarily.” The expectation that CPR’s drop-deck center-beam flat cars will spend more than 50 percent of their useful lifespan in the United States is not relevant to the § 272 analysis. If the cars are entering the United States for a limited time—that is, they are not entering permanently—and are entering only for the purpose of engaging in international commerce—that is, they are entering to unload foreign goods and/or to load domestic goods destined for foreign markets—they are entering “temporarily” for the purposes of § 272 regardless of the length of their stay within the jurisdiction of the United States.

Furthermore, neither the magnitude of the benefit derived by CPR from use of the cars nor the burden imposed on NSC from the carve-out of CPR’s use from the scope of its right to exclude under the ’575 patent is relevant to the § 272 analysis. We agree with the reasoning that the court in Cali put forward to address the patentee’s argument that:

[T]he particular airlines involved, given the magnitude of their carrier operations between foreign countries and this country, are such that the airlines are comparable to American airlines in the extent of their use of the
article of Cali’s patent, and that, in consequence, the subtraction from the grant to Cali of the right to exclude others from the use of his patent is a very great subtraction and one hardly tolerable under the statutory and treaty language, which might be thought to deal only with relatively unimportant (“Temporary” and “accidental”) invasions of the patent right that are without commercial significance. That subtraction, although large, appears nevertheless plainly to be what the statutory and treaty immunities intend *** .

Id. at 1127.

Therefore, we hold that NSC has not demonstrated that CPR’s § 272 defense lacks “substantial merit” because the entering “temporarily” condition is not satisfied. NSC does, however, advance one argument that, although not considered by the district court, raises a question regarding whether CPR will succeed on the merits of the § 272 noninfringement defense. At the preliminary injunction hearing, Mr. Buggs, the general manager of car management with CPR, testified that “sometimes *** the U.S. [r]ailway will grab one of our [center-beam flat] cars with[ou]t our permission *** [a]nd *** they will move it, you know, load it to another point.” Because CPR acknowledged that its newly acquired dropdeck center-beam flat cars will be used in the same fashion that its current fleet of center-beam flat cars is used, NSC uses the testimony of Mr. Buggs to allege that the GBRX 20003 cars enter the United States in part with a purpose to engage in domestic, rather than international, commerce. Certainly, the unforeseen “grabbing” of one of CPR’s large fleet of cars without CPR’s permission cannot lead to a reasonable inference that CPR had a purpose to engage in commerce other than international commerce. However, if CPR regularly condones such repeated “grabbing” of its cars for domestic commerce and CPR receives remuneration for the “grabbing” that is substantial in relation to the income that the cars produce through their use in international commerce, a factfinder could infer that CPR’s intent is not to engage in essentially international commerce. Based on the current record, however, we hold that NSC’s allegations do not deprive CPR’s § 272 defense of substantial merit.

D

Third, the district court held that the drop-deck center-beam rail car invention was not “used exclusively for the needs of the *** vehicle” as § 272 requires. Framing § 272 narrowly around the holdings of Brown, Cali, and Hughes, the district court concluded that for an invention to be “used exclusively for the needs of the *** vehicle,” it must “help propel the trains, help in positioning the trains, or help in [some] other way to make the trains work.” Because the invention of the ’575 patent defines the structure of the rail car, rather than an aspect of the locomotive’s propulsion system, the district court concluded that the use of invention in the ’575 patent in the accused rail car did not fall within the scope of § 272.

13 The transcript uses the word “with” rather than “without.” CPR has argued that this is a typographical error; NSC does not contest this argument on appeal. Because we merely note the unsettled nature of the parties dispute on this issue, our characterization of the content of the testimony is not intended to be binding.
We disagree that the “exclusively for the needs of the *** vehicle” language in § 272 should be interpreted so narrowly as to exclude inventions such as the ’575 patent pertaining to the construction of a vehicle. The district court erroneously overlaid the concept of “propulsive needs” onto the statute; “structural needs” are also encompassed within the plain meaning of the statute.

This reading of § 272 is consistent with Brown and the Paris Convention, the sources of law to which Congress referred in enacting § 272. In Brown, the Supreme Court characterized its own holding of noninfringement more broadly to pertain to inventions “used in the construction, fitting out, or equipment” of a vessel. 60 U.S. (19 How.) at 198 (emphasis added). Likewise, the Paris Convention extends the scope of noninfringing uses to inventions used “in the construction or operation of *** land vehicles *** or of accessories of such *** land vehicles.” Paris Convention for the Protection of Industrial Property, 21 U.S.T. at 1639 (emphasis added). The text of the Paris Convention expressly applies to inventions used in either the construction or the operation of a vehicle, whereas the district court limited the meaning of the “exclusively for the needs of the *** vehicle” language in § 272 to only the latter.\footnote{Furthermore, the ’575 patent itself describes the invention in question as an invention related to the stability—and thus the propulsion—of the train. See ’575 patent, col. 2, ll. 46-49 (“The reduced center of gravity *** significantly improves the track worthiness and ride stability of the car.”).}

E

Fourth and finally, the district court held that the use of the invention in the ’575 patent in the GBRX 20003 did not qualify as a noninfringing use under § 272 because the language of § 272 requires that the invention not be “offered for sale or sold in *** the United States.” The district court found that Greenbrier had “offered the accused rail car for sale to at least three different companies in the United States,” and that “CPR, itself, may sell the accused rail cars to leasing companies in the United States.” We conclude that neither line of reasoning is sufficient to uphold the district court’s preliminary injunction against Canadian Pacific.

First, insofar as it relied on sales by Greenbrier, who is not a party to this suit, of rail cars in which CPR never had any financial interest, the district court erred in its construction of the statute. The “offered for sale or sold in *** the United States” provision of § 272 does not apply to sales made by third parties of embodiments of the invention other than those that temporarily enter the United States.

Again, the language of Brown is instructive to interpret the meaning of the “offered for sale or sold in *** the United States” language in § 272. In Brown, the Court noted that the captain would be liable under the patent laws “if the captain had sold [the invention] there,” namely in the port of Boston. 60 U.S. (19 How.) at 196. This concept—the prohibition on selling the very embodiment of the invention that had been used in the vessel or vehicle while the vehicle was temporarily or accidentally in the United States—has been codified in the language of § 272 that
permits the statute’s application only “if the invention *** is not offered for sale or sold in *** the United States.” 35 U.S.C. § 272.

Second, insofar as it relied on its finding of fact that Canadian Pacific “may sell the accused rail cars to leasing companies in the United States,” we conclude that the district court’s discretion involved a clear error of judgment.

We accept the district court’s finding of fact that CPR “may” seek to finance its purchase of the fleet of GBRX 20003 rail cars through a sale-leaseback arrangement in which CPR would sell the cars to a United States leasing company and then lease the cars back through a capital or operating lease. As the district court itself found, “[n]o decision has been made about the ownership structure of the dropped deck center beam flat cars” to be operated by CPR. Furthermore, we agree with the district court’s implicit conclusion that a sale-leaseback arrangement between CPR and a U.S. company would, even at this preliminary-injunction phase, remove substantial merit from CPR’s defense of noninfringement based on § 272. Not only might the sale-leaseback arrangement constitute a sale of “the invention,” as prohibited by the language in the second half of § 272, it also might transform the rail car into a vehicle of the United States and thus remove the use of the invention from the scope of the uses provided for in the first half of § 272.

However, a finding that CPR “may” engage in such conduct is, alone, insufficient to deprive CPR’s § 272 defense of substantial merit. If at some point in the future NSC can show that a decision on ownership has been reached, and that the chosen ownership structure would deprive CPR’s § 272 defense of substantial merit, NSC may request appropriate relief at that time.

In conclusion, upon considered review of the each element of the district court’s reasoning, we hold that the district court abused its discretion in holding that Canadian Pacific’s § 272 defense lacked substantial merit.

...
A. Overview of Electronic Mail Technology

Traditional email systems operate in the following manner: To send an email, a user begins by composing a message in his or her email client. An “email client” is a user interface, such as Microsoft Outlook, Eudora, or Hotmail, that organizes and displays a user’s email messages and provides the user with a means of creating and sending email messages. The message begins with a specific destination address, e.g., jdoe@***.com, that corresponds to the recipient’s user identification, “jdoe,” and his or her internet service provider (“ISP” or “host”), “***.com.” See generally Andrew S. Tanenbaum, Computer Networks 592-611 (4th ed. 2003). When the message is sent, it is transferred first from the sender’s machine to his or her ISP. Id. at 607. The sender’s host then uses a domain name server to identify the recipient’s ISP mail server and its associated internet protocol (“IP”) address. Id. A connection is then established by the sender’s host with the recipient’s ISP mail server, facilitating transfer of the message. Id. at 607-08. The message is next sorted by the recipient’s ISP mail server into the recipient’s particular “mailbox,” where it is stored until the recipient initiates a connection with the server and downloads the message off the server onto his or her personal machine. This configuration is commonly referred to as a “pull” system because emails cannot be distributed to the user’s machine without a connection being initiated by the user to “pull” the messages from the mail server.

B. Problems With the Prior Art Systems

As societal dependence on email and computers increased throughout the 1990s, so did the demand for mobile internet access. See generally Richard Duffy & Denis Gross, World Without Wires, 22 Communication Int’l 72 (June 1995) (describing “user demand” as “one of the most important driving factors behind the mobile data market”). The increased portability of computers via laptop machines exacerbated this demand. See id. Available methods of remote internet access were cumbersome and inefficient for the traveling businessperson, however, as the patents-in-suit explain:

As personal computers are used more frequently by business travellers, the problem of electronic mail delivery becomes considerably more difficult. A business traveler carrying a portable PC has great difficulty in finding a telephone jack to connect the PC to fetch electronic mail from either a host computer or a gateway switch. Connections for a PC’s modem are difficult to find in airports. *** Hotels and motels often have internal PABX’s that prevent calls from automatically being placed by the user’s PC to electronic mail gateway switches to receive information. *** The inability to find an appropriate connection to connect the PC modem when travelling has contributed to the degradation of electronic mail reception when the recipient is travelling.

’960 patent, col. 3, l. 60 – col. 4, l. 12. RIM’s technical documentation for its BlackBerry products echoes the undesirability of these constraints:

Typically, mobile professionals use a laptop when traveling and dial in to the corporate email server from a hotel room to manage an inbox full of email. The more adventurous use special software to send email notifica-
tion to a pager or cell phone so they know what is in their inbox before spending the time and effort to dial in. Focus groups and market research on mobile email revealed common complaints with dialing in—the inconvenience of lugging a laptop around just for email; the trouble of finding a connection and dialing out of the hotel; the difficulty of negotiating corporate dial-in security; and the cost of phone charges when dialing in to the corporate server.


C. The Patents-in-Suit

Inventors Thomas J. Campana [and others] (collectively “Campana”) developed an electronic mail system that was claimed in the '960 patent [and its continuation patents]. … As continuations of that single parent application, these patents contain the same written descriptions as the '960 patent. NTP now owns these five patents-in-suit.

Campana’s particular innovation was to integrate existing electronic mail systems with RF wireless communications networks. In simplified terms, the Campana invention operates in the following manner: A message originating in an electronic mail system may be transmitted not only by wireline but also via RF, in which case it is received by the user and stored on his or her mobile RF receiver. The user can view the message on the RF receiver and, at some later point, connect the RF receiver to a fixed-destination processor, e.g., his or her personal desktop computer, and transfer the stored message. Intermediate transmission to the RF receiver is advantageous because it “eliminat[es] the requirement that the destination processor [be] turned on and carried with the user” to receive messages. Instead, a user can access his or her email stored on the RF receiver and “review *** its content without interaction with the destination processor,” while reserving the ability to transfer the stored messages automatically to the destination processor. The patents-in-suit do not disclose a method for composing and sending messages from the RF receiver.

D. The Accused System

RIM is a Canadian corporation with its principal place of business in Waterloo, Ontario. RIM sells the accused BlackBerry system, which allows out-of-office users to continue to receive and send electronic mail, or “email” communications, using a small wireless device. The system utilizes the following components: (1) the BlackBerry handheld unit (also referred to as the “BlackBerry Pager”); (2) email redirector software (such as the BlackBerry Enterprise Server (“BES”), the Desktop Redirector, or the Internet Redirector); and (3) access to a nationwide wireless network (such as Mobitex, DataTAC, or GPRS).

The BlackBerry system uses “push” email technology to route messages to the user’s handheld device without a user-initiated connection. There are multiple BlackBerry email “solutions” that interface with different levels of the user’s email system. In the Desktop solution, the BlackBerry email redirector software, the Desktop Redirector, is installed on the user’s personal computer. In the Corporate solu-
tion, different BlackBerry email redirector software, the BES program, is installed on the organizational user’s mail server, where it can function for the benefit of the multiple users of that server. Also at issue in this case is RIM’s Internet solution of the BlackBerry system. The Internet solution operates in a manner similar to the Corporate solution, but it executes a different email redirector software, Internet Redirector. In either version, the BlackBerry email redirector software merges seamlessly with the user’s existing email system. The operation of the email redirector software is transparent to the user’s desktop email client and the organizational user’s mail server. That is, the user’s email system does not recognize or incorporate the BlackBerry wireless system into its operation. No modification of the underlying email system is required to run RIM’s wireless email extension. When new mail is detected in the Desktop solution, the Desktop Redirector is notified and retrieves the message from the mail server. It then copies, encrypts, and routes the message to the BlackBerry “Relay” component of RIM’s wireless network, which is located in Canada. In the Corporate solution, the BES software performs this same function but intercepts the email before the message reaches the individual user’s personal computer. The individual user’s personal computer need not be turned on for the BES software to properly redirect the user’s emails. However, the user retains some control over message forwarding by using the BlackBerry “Desktop Manager.” This additional software permits the user to specify his or her email redirection preferences. In both systems, the message travels through the BlackBerry Relay, where it is translated and routed from the processors in the user’s email system to a partner wireless network. That partner network delivers the message to the user’s BlackBerry handheld, and the user is “notified virtually instantly” of new email messages. This process, accomplished without any command from the BlackBerry user, is an example of “push” email architecture. There are significant advantages to “push” email architecture. Most importantly, the user is no longer required to initiate a connection with the mail server to determine if he or she has new email. As RIM’s technical literature explains, “[b]y having the desktop connect to the user, time spent dialing up and connecting to the desktop (possibly to find that there is no new email) is eliminated as users *** are notified virtually instantly of important messages, enabling the user to respond immediately.”

RIM’s system also permits users to send email messages over the wireless network from their handhelds. This functionality is achieved through the integration of an RF transmitter and a processor in the BlackBerry handheld unit. The processor allows the user to manipulate, view, and respond to email on his or her BlackBerry handheld. Sending a message from the handheld requires the same steps as the process for receiving email, only in reverse. When the user composes a message on his or her handheld, it is sent back to that user’s desktop machine over the partner and BlackBerry wireless networks. The BlackBerry email redirector software then retrieves the outgoing message from the user’s mail server and places it in the user’s desktop email software, where it is dispersed through normal channels. In this way, messages sent from the BlackBerry handheld are identical to messages sent from the user’s desktop email—they originate from the same address and also appear in the “sent mail” folder of the user’s email client.
E. Procedural History

On November 13, 2001, NTP filed suit against RIM ... alleg[ing] that over forty system and method claims from its several patents-in-suit had been infringed by various configurations of the BlackBerry system (comprised of the numerous handheld units; the BES, the Desktop Redirector, and the ISP Redirector software; and the associated wireless networks).

In an Order dated August 14, 2002, the district court construed thirty-one disputed claim terms. ... A series of summary judgment motions followed the court’s Markman decision. Setting forth several alternate theories, RIM asked for summary judgment of both non-infringement and invalidity. [One of t]he issues raised in ... RIM’s summary judgment motions remain[s] relevant on appeal: RIM argued ... that the physical location of the “Relay” component of the BlackBerry system put RIM’s allegedly infringing conduct outside the reach of 35 U.S.C. § 271. The district court denied all of RIM’s summary judgment motions.

... 

II. Analysis

2. Section 271(a)

Section 271(a) of title 35 sets forth the requirements for a claim of direct infringement of a patent. It provides:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

35 U.S.C. § 271(a). The territorial reach of section 271 is limited. Section 271(a) is only actionable against patent infringement that occurs within the United States. See Pellegrini v. Analog Devices, Inc., 375 F.3d 1113, 1117 (Fed. Cir. 2004) (“[As] the U.S. Supreme Court explained nearly 150 years ago in Brown v. Duchesne, 60 U.S. (19 How.) 183 (1856), *** the U.S. patent laws do not, and were not intended to, operate beyond the limits of the United States.”); Rotec Indus., Inc. v. Mitsubishi Corp., 215 F.3d 1246, 1251 (Fed. Cir. 2000) (stating that “extraterritorial activities *** are irrelevant to the case before us, because ‘the right conferred by a patent under our law is confined to the United States and its territories, and infringement of this right cannot be predicated on acts wholly done in a foreign country’”) (emphasis added) (quoting Dowagiac Mfg. Co. v. Minn. Moline Plow Co., 235 U.S. 641, 650 (1915)).

Ordinarily, whether an infringing activity under § 271(a) occurs within the United States can be determined without difficulty. This case presents an added degree of complexity, however, in that: (1) the “patented invention” is not one single device, but rather a system comprising multiple distinct components, or a method with multiple distinct steps; and (2) the nature of those components or steps permits their function and use to be separated from their physical location.
In its complaint, NTP alleged that RIM had infringed its patents by “making, using, selling, offering to sell and importing into the United States products and services, including the Defendant’s BlackBerry products and their related software ***.” NTP’s theory of infringement tracks the language of § 271(a). In the district court, RIM moved for summary judgment of noninfringement, arguing that it could not be held liable as a direct infringer under § 271(a). According to RIM, the statutory requirement that the allegedly infringing activity occur “within the United States” was not satisfied because the BlackBerry Relay component of the accused system is located in Canada. The Relay component is alleged to meet the “interface” or the “interface switch” limitation in [four of] the … patents. RIM’s argument based on the location of its Relay outside the United States does not apply to the asserted claims of [one of] the … patent[s] because those claims do not include the “interface” or “interface switch” limitation.

The district court declined to grant summary judgment in RIM’s favor. The court agreed that “to establish direct infringement under § 271(a), NTP must show that RIM practiced all of the steps of the process patented in the Campana inventions in the United States.” However, because there remained “a genuine dispute *** with regards to whether RIM operates a Relay facility in Virginia,” the court decided it could not resolve this issue on summary judgment. Subsequently, during trial, the court changed its position and specifically held that “the fact that the BlackBerry relay is located in Canada is not a bar to infringement in this matter.” The court therefore instructed the jury that “the location of RIM’s Relay in Canada does not preclude infringement.” In the district court, the jury found direct, induced, and contributory infringement by RIM on all asserted claims. The asserted claims included both systems and methods for transmitting an email message between an originating processor and a destination processor. By holding RIM liable for contributory infringement and inducing infringement, the jury necessarily found that its customers are direct infringers of the claimed systems and methods. Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed. Cir. 2004) (“Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement, though the direct infringer is typically someone other than the defendant accused of indirect infringement.”).

On appeal, RIM argues that the district court erred in its interpretation of the infringement statute. RIM does not appeal the jury’s finding that its customers use, i.e., put into service, its systems and methods for transmitting email messages. RIM has, however, appealed whether any direct infringement, by it or its customers, can be considered “within the United States” for purposes of section 271(a). Citing the Supreme Court’s decision in DeepSouth, RIM contends that an action for infringement under section 271(a) may lie only if the allegedly infringing activity occurs within the United States. RIM urges that, in this case, that standard is not met because the BlackBerry Relay component, described by RIM as the “control point” of the accused system, is housed in Canada. For section 271(a) to apply, RIM asserts that the entire accused system and method must be contained or conducted within the territorial bounds of the United States. RIM thus contends that there can be no
direct infringement as a matter of law because the location of RIM’s Relay outside the United States precludes a finding of an infringing act occurring within the United States.

This court reviews the statutory construction of a district court de novo. Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996). In our interpretation of the statute, we “give the words of a statute their ordinary, contemporary, common meaning, absent an indication Congress intended them to bear some different import.” Williams v. Taylor, 529 U.S. 420, 431 (2000). We begin with the words of the statute, see Trayco, Inc. v. United States, 994 F.2d 832, 836 (Fed. Cir. 1993), but may consult dictionaries, see Bayer AG v. Housey Pharms., Inc., 340 F.3d 1367, 1371 (Fed. Cir. 2003), and legislative history, see Neptune Mut. Ass’n Ltd. of Bermuda v. United States, 862 F.2d 1546, 1549 (Fed. Cir. 1988), if necessary to construe the statute.

The question before us is whether the using, offering to sell, or selling of a patented invention is an infringement under § 271(a) if a component or step of the patented invention is located or performed abroad. … Pursuant to § 271(a), whoever without authority “uses, offers to sell, or sells any patented invention, within the United States *** during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). The grammatical structure of the statute indicates that “within the United States” is a separate requirement from the infringing acts clause. Thus, it is unclear from the statutory language how the territoriality requirement limits direct infringement where the location of at least a part of the “patented invention” is not the same as the location of the infringing act.

RIM argues that Deepsouth answers this question. However, Deepsouth did not address this issue. In Deepsouth, the Supreme Court considered whether § 271(a) prevented, as direct infringement, the domestic production of all component parts of a patented combination for export, assembly, and use abroad. 406 U.S. at 527. The Court held that the export of unassembled components of an invention could not infringe the patent. Id. at 529. The Court said that it could not “endorse the view that the ‘substantial manufacture of the constituent parts of a machine’ constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.” Id. at 528. Thus, the Court concluded that the complete manufacture of the operable assembly of the whole within the United States was required for infringement by making under § 271(a). In that case, however, both the act of making and the resulting patented invention were wholly outside the United States. By contrast, this case involves a system that is partly within and partly outside the United States and relates to acts that may be occurring within or outside the United States.

Although Deepsouth does not resolve these issues, our predecessor court’s decision in Decca Ltd. v. United States, 544 F.2d 1070 (Ct. Cl. 1976), is instructive. In Decca, the plaintiff sued the United States for use and manufacture of its patented invention under 28 U.S.C. § 1498. The claimed invention was a radio navigation system requiring stations transmitting signals that are received by a receiver, which then calculates position by the time difference in the signals. At the time of the suit, the United States was operating three such transmitting stations, one of which was
located in Norway and thus was outside the territorial limits of the United States. Only asserted claim 11 required three transmitting stations. Thus, in considering infringement of claim 11, the court considered the extraterritorial reach of the patent laws as applied to a system in which a component was located outside the United States. The court recognized that *Deepsouth* did not address this issue. *Id.* at 1081. In analyzing whether such a system was “made” in the United States, however, the court focused on the “operable assembly of the whole” language from *Deepsouth* and concluded that “[t]he plain fact is that one of the claimed elements is outside of the United States so that the combination, as an operable assembly, simply is not to be found solely within the territorial limits of this country.” *Id.* at 1082.

The court recognized that what was located within the United States was as much of the system as was possible, but the court reached no clear resolution of whether the accused system was “made” within the United States. Nevertheless, the court said, “Analyzed from the standpoint of a use instead of a making by the United States, a somewhat clearer picture emerges.” *Id.* The court concluded that “it is obvious that, although the Norwegian station is located on Norwegian soil, a navigator employing signals from that station is, in fact, ‘using’ that station and such use occurs wherever the signals are received and used in the manner claimed.” *Id.* at 1083. In reaching its decision, the court found particularly significant “the ownership of the equipment by the United States, the control of the equipment from the United States and *** the actual beneficial use of the system within the United States.” *Id.* Although *Decca* was decided within the context of § 1498, which raises questions of use by the United States, the question of use within the United States also was implicated because direct infringement under § 271(a) is a necessary predicate for government liability under § 1498. *Motorola, Inc. v. United States*, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984).

*Decca* provides a legal framework for analyzing this case. As our predecessor court concluded, infringement under § 271(a) is not necessarily precluded even though a component of a patented system is located outside the United States. However, as is also evident from *Decca*, the effect of the extraterritorial component may be different for different infringing acts. In *Decca*, the court found it difficult to conclude that the system had been made within the United States but concluded that the system had been used in the United States even though one of the claim limitations was only met by including a component located in Norway. Not only will the analysis differ for different types of infringing acts, it will also differ as the result of differences between different types of claims. Because the analytical frameworks differ, we will separately analyze the alleged infringing acts, considering first the system claims and then the claimed methods.

a. “uses *** within the United States”

The situs of the infringement “is wherever an offending act [of infringement] is committed.” *N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) (”[Section 271] on its face clearly suggests the conception that the ‘tort’ of patent infringement occurs where the offending act is committed and not where the injury is felt.”). The situs of the infringing act is a “purely physical occurrence[].” *Id.* In terms of the infringing act of “use,” courts have interpreted the
term “use” broadly. In *Bauer & Cie v. O’Donnell*, 229 U.S. 1 (1913), the Supreme Court stated that “use,” as used in a predecessor to title 35, is a “comprehensive term and embraces within its meaning the right to put into service any given invention.” *Id.* at 10-11. The ordinary meaning of “use” is to “put into action or service.” *Webster’s Third New International Dictionary* 2523 (1993). The few court decisions that address the meaning of “use” have consistently followed the Supreme Court’s lead in giving the term a broad interpretation. *E.g.*, *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that testing is a “use”), superseded-in-part by 35 U.S.C. § 271(e).

The use of a claimed system under § 271(a) is the place at which the system as a whole is put into service, *i.e.*, the place where control of the system is exercised and beneficial use of the system obtained. *See Decca*, 544 F.2d at 1083. Based on this interpretation of § 271(a), it was proper for the jury to have found that use of NTP’s asserted system claims occurred within the United States. RIM’s customers located within the United States controlled the transmission of the originated information and also benefited from such an exchange of information. Thus, the location of the Relay in Canada did not, as a matter of law, preclude infringement of the asserted system claims in this case.

RIM argues that the BlackBerry system is distinguishable from the system in *Decca* because the RIM Relay, which controls the accused systems and is necessary for the other components of the system to function properly, is not located within the United States. While this distinction recognizes technical differences between the two systems, it fails to appreciate the way in which the claimed NTP system is actually used by RIM’s customers. When RIM’s United States customers send and receive messages by manipulating the handheld devices in their possession in the United States, the location of the use of the communication system as a whole occurs in the United States. This satisfactorily establishes that the situs of the “use” of RIM’s system by RIM’s United States customers for purposes of § 271(a) is the United States. Therefore, we conclude that the jury was properly presented with questions of infringement as to NTP’s system claims containing the “interface” or “interface switch” limitation … .

We reach a different conclusion as to NTP’s asserted method claims. Under § 271(a), the concept of “use” of a patented method or process is fundamentally different from the use of a patented system or device. *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing “the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps. *** [A process] consists of doing something, and therefore has to be carried out or performed.”); *see Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993) (“The law is unequivocal that the sale of equipment to perform a process is not a sale of the process within the meaning of section 271(a).”). Although the Supreme Court focused on the whole operable assembly of a system claim for infringement in *Deepsouth*, there is no corresponding whole operable assembly of a process claim. A method or process consists of one or more operative steps, and, accordingly, “[i]t is well established that a patent for a method or
process is not infringed unless all steps or stages of the claimed process are utilized.” *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976).

Because a process is nothing more than the sequence of actions of which it is comprised, the use of a process necessarily involves doing or performing each of the steps recited. This is unlike use of a system as a whole, in which the components are used collectively, not individually. We therefore hold that a process cannot be used “within” the United States as required by § 271(a) unless each of the steps is performed within this country. In the present case, each of the asserted method claims of [three of] the … patents recites a step that utilizes an “interface” or “interface switch,” which is only satisfied by the use of RIM’s Relay located in Canada. Therefore, as a matter of law, these claimed methods could not be infringed by use of RIM’s system.

Thus, we agree with RIM that a finding of direct infringement by RIM’s customers under § 271(a) of the method claims reciting an “interface switch” or an “interface” is precluded by the location of RIM’s Relay in Canada. As a consequence, RIM cannot be liable for induced or contributory infringement of the asserted method claims, as a matter of law.

b. “offers to sell, or sells”

Because we conclude that RIM’s customers could not have infringed the asserted method claims of [three] patents under the “use” prong of § 271(a), and thus, could not have provided the necessary predicate for the charges of induced or contributory infringement of those claims, we must consider whether RIM could have directly infringed the method claims under the “sell” or “offer to sell” prongs of § 271(a). The cases cited by RIM are concerned primarily with the “use” and “make” prongs of § 271(a) and do not directly address the issue of whether a method claim may be infringed by selling or offering to sell within the meaning of § 271(a).

Because the relevant precedent does not address the issue of whether a sale of a claimed method can occur in the United States, even though the contemplated performance of that method would not be wholly within the United States, the issue is one of first impression. We begin with the language of the statute. Section 271(a) does not define “sells” or “offers to sell,” nor does the statute specify which infringing acts apply to which types of claims. Section 271(a) was merely a codification of the common law of infringement that had developed up to the time of passage of the 1952 Patent Act. It was not meant to change the law of infringement. *Deepsouth*, 406 U.S. at 530 n.10. A claim directed to a method or process, although somewhat controversial in the Nineteenth Century, is now a well-established form of claiming. See *In re Tarczy-Hornoch*, 397 F.2d 856, 857-65 (CCPA 1968) (describing the evolution of Supreme Court precedent concerning process claims). Nevertheless, the precise contours of infringement of a method claim have not been clearly established.

In *Enercon GmbH v. International Trade Commission*, 151 F.3d 1376 (Fed. Cir. 1998), this court considered the meaning of the phrase “sale for importation” in the International Trade Commission’s governing statute, 19 U.S.C. § 1337. Because the term “sale” was not defined in the statute, we assumed that Congress in-
tended to give the term its ordinary meaning, *id.* at 1381. In considering the ordinary meaning, we looked to dictionaries and to the Uniform Commercial Code. *Id.* at 1382. We employ a similar methodology here, looking to the ordinary meaning of the term “sale.” The definition of “sale” is: “1. The transfer of property or title for a price. 2. The agreement by which such a transfer takes place. The four elements are (1) parties competent to contract, (2) mutual assent, (3) a thing capable of being transferred, and (4) a price in money paid or promised.” *Black’s Law Dictionary* 1337 (7th ed. 1999). Thus, the ordinary meaning of a sale includes the concept of a transfer of title or property. The definition also requires as the third element “a thing capable of being transferred.” It is difficult to apply this concept to a method claim consisting of a series of acts. See *Minton v. Nat’l Ass’n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1378 (Fed. Cir. 2003) (“[A] process is a series of acts, and the concept of sale as applied to those acts is ambiguous.”). It is difficult to envision what property is transferred merely by one party performing the steps of a method claim in exchange for payment by another party. Moreover, performance of a method does not necessarily require anything that is capable of being transferred.

Congress has consistently expressed the view that it understands infringement of method claims under § 271(a) to be limited to use. The committee reports surrounding the passage of the Process Patents Amendments Act of 1987 [creating a new subsection, 35 U.S.C. § 271(g)] indicate that Congress did not understand all of the infringing acts in § 271(a) to apply to method claims. The Senate Report explains, “Under our current patent laws, a patent on a process gives the patentholder the right to exclude others from using that process in the United States without authorization from the patentholder. The other two standard aspects of the patent right—the exclusive right to make or sell the invention—are not directly applicable to a patented process.” S. Rep. No. 100-83, at 30 (1987). The House Report expresses a similar view: “With respect to process patents, courts have reasoned that the only act of infringement is the act of making through the use of a patented process *** .” H.R. Rep. No. 99-807, at 5 (1986). Although this issue has not been directly addressed, this court expressed a similar view in *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993). In that case, we said, “A method claim is directly infringed only by one practicing the patented method.” *Id.* at 775.

In 1994, Congress passed legislation to implement the Uruguay Round of the General Agreement on Tariffs and Trade. Uruguay Round Agreements Act, 108 Stat. 4809 (1994). That legislation modified § 271(a) to include the infringing acts of offering to sell and importing into the United States. § 533, 108 Stat. at 4988. The portion of the Uruguay Round being implemented in the modification of § 271(a) was the Agreement on Trade-Related Aspects of Intellectual Property Rights. That agreement clearly spells out the rights to be protected. It states:

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and
from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 28, H.R. Doc. No. 103-316, at 1634 (1994) (footnote omitted). The agreement makes clear that claimed processes are to be directly protected only from “the act of using the process.” The joint committee report from the Senate reflects the same understanding: “The list of exclusive rights granted to patent owners is expanded to preclude others from offering to sell or importing products covered by a U.S. patent or offering to sell the products of patented processes.” S. Rep. 103-412, at 230 (1994). Thus, the legislative history of § 271(a) indicates Congress’s understanding that method claims could only be directly infringed by use.

In the context of the on sale bar, we have held that a method claim may be invalid if an offer to perform the method was made prior to the critical date. *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (“The on sale bar rule applies to the sale of an ‘invention,’ and in this case, the invention was a process, as permitted by § 101. As a result, the process involved in this case is subject to § 102(b).”); see also *Robotic Vision Sys., Inc. v. View Eng’g, Inc.*, 249 F.3d 1307 (Fed. Cir. 2001) (affirming invalidity of claimed method under on sale bar where device capable of performing claimed method was sold). Nevertheless, we have previously “decline[d] to import the authority construing the ‘on sale’ bar of § 102(b) into the ‘offer to sell’ provision of § 271(a).” *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1379 n.4 (Fed. Cir. 1998). As the Supreme Court cautioned in *Deepsouth*, 406 U.S. at 531: “We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought.” The indication we have from Congress on infringement by selling or offering to sell method claims shows that it believes the beachhead is narrow.

In this case, we conclude that the jury could not have found that RIM infringed the asserted method claims under the “sells” or “offers to sell” prongs of § 271(a). We need not and do not hold that method claims may not be infringed under the “sells” and “offers to sell” prongs of § 271(a). Rather, we conclude only that RIM’s performance of at least some of the recited steps of the asserted method claims as a service for its customers cannot be considered to be selling or offering to sell the invention covered by the asserted method claims. The sale or offer to sell handheld devices is not, in and of itself, enough. Thus, we conclude as a matter of law that RIM did not sell or offer to sell the invention covered by NTP’s method claims within the United States.

c. “import into the United States”

Because the jury’s instruction on direct infringement by RIM included the act of importing, we must consider next whether the jury could have found that RIM imported any of the processes covered by the asserted method claims in violation of § 271(a). Like the sell and offer to sell provisions discussed above, the question of whether a method claim can be infringed by importation is a difficult one conceptually. The legislative history cited with respect to the sell and offer to sell provisions
indicates that Congress did not consider the “import” prong of § 271(a) to apply to method claims. However, we need not decide that broad issue. We hold only that for the same reasons that the jury could not have found that RIM infringed the method claims under the sale or offer for sale prongs, it could not have found infringement by importation under the facts of this case.

…

**Meyer Intellectual Properties Ltd. v. Bodum, Inc.**

690 F.3d 1354 (Fed. Cir. 2012)

O’Malley, Judge:

In this patent case, Meyer Intellectual Properties Limited and Meyer Corporation, U.S. (collectively, “Meyer”) filed suit against Bodum, Inc. (“Bodum”) … alleging that Bodum infringed two of Meyer’s patents, both of which are directed to a method for frothing milk: U.S. Patent Nos. 5,780,087 and 5,939,122. …

The district court granted Meyer’s motions for summary judgment that Bodum’s products infringed the patents-in-suit. … The jury returned a verdict in favor of Meyer, finding that the patents-in-suit were not proven to be invalid, finding that Bodum’s infringement was willful, and awarding Meyer damages in the amount of $50,000. The district court subsequently denied Bodum’s post-trial motions for judgment as a matter of law (“JMOL”) and granted Meyer’s motion requesting enhanced damages and attorney fees.

Bodum appeals from the district court’s final judgment awarding damages and attorney fees to Meyer in the amount of $906,487.56. On appeal, Bodum challenges several of the court’s rulings … [including] granting summary judgment in favor of Meyer on infringement … . For the reasons explained below, we reverse-in-part, vacate-in-part, and remand.

Background

A. Factual Background

1. The Patents-in-Suit

Frank Brady (“Brady”) is the sole inventor of the ’087 and ’122 Patents. For approximately ten years, from 1986 to 1996, Brady was an independent sales representative for Bodum, a company that designs and sells housewares products, including coffee makers, milk frothers, and other kitchen products. In that capacity, and as the Chief Executive Officer of Brady Marketing Company, Inc., Brady marketed and sold a number of Bodum’s household products, including Bodum’s French press coffee makers. Brady explained that he first conceived of a frother using aeration instead of steam in the mid-1990s, and that he introduced it for sale at a trade show in May 1996. Around that same time, Brady began selling his frothers through his company BonJour, Inc. (“BonJour”).

amended the claim to provide: (1) a dimensional limitation requiring that the container have a height that is at least two times the diameter; and (2) a plunger with a screen and a spring, where the spring is “positioned about the circumference of the plunger body such that the spring is biased to hold the screen in place in contact with, though not sealably connected to, the container.” With these changes, Claim 1 of the '087 Patent was allowed.

While the application that resulted in the '087 Patent was pending, Brady filed a continuation application that later became the '122 Patent. The '122 Patent issued on August 17, 1999.

The patents-in-suit, which share a common specification, are directed to a method for frothing liquids such as milk. Specifically, the patents relate to “an apparatus and method for frothing, which allows the user to obtain foamy, frothed milk without the use of a complicated steamer device.” …

Generally speaking, the claims disclose four steps: (1) providing a container that has a height to diameter aspect ratio of 2:1; (2) pouring liquid (e.g., milk) into the container; (3) introducing a plunger that includes at least a rod and plunger body with a screen; and (4) pumping the plunger to aerate the liquid.

2. Bodum’s Accused Products

Meyer accuses three of Bodum’s milk frothers of infringement: (1) the Chambord Frother Model No.1964; (1) the Aerius Frother Model No. 1364; and (3) the Shin Bistro Frother Model No. 10492. Bodum began selling a first generation of accused milk frothers—referred to as the Version 1 frothers—in 1999. The Version 1 frothers departed from Bodum’s previous non-electric milk frothers in that: (1) the carafe was taller and thinner; and (2) the plunger had a different construction involving a mesh and spring design. The following images show a comparison between Bodum’s Version 1 Chambord Frother and the Figures from Meyer’s '087 Patent:
B. Procedural History

In May 2005, Brady sold his company—BonJour—to Meyer. In the sale, BonJour transferred its intellectual property rights to Meyer, and it is undisputed that Meyer owns the patents-in-suit.

On November 20, 2006, Meyer filed suit against Bodum ... alleging infringement of the patents-in-suit. In the Complaint, Meyer alleged that Bodum “has been and still is using, selling, offering for sale and/or importing one or more milk frother products for frothing liquids that infringe, directly, indirectly, contributorily and/or by inducement” the ’087 Patent and the ’122 Patent. ...

Roughly six months after it was served with the complaint, Bodum ceased manufacturing its Version 1 frothers and transitioned to Version 2 frothers with a new plunger design. Bodum did not change the name or designation of its frother products. According to Bodum, “[u]nlike the Version 1 plunger, the Version 2 plunger does not have a spring or other biasing element that holds the screen against the inside wall of the container or housing, and the screen does not extend beyond the diameter of the plunger plate.” Instead, the Version 2 plunger contains an O-ring around the circumference of the plunger body. Bodum subsequently removed the O-ring from the Version 2 frother and began selling the new design as Version 3 in July 2008.

On September 2, 2008, Meyer moved for partial summary judgment, arguing that, by providing its Version 1 frothers along with instructions for their use, Bodum induced others—specifically Meyer’s own expert Albert Karvelis—to infringe the patents-in-suit. In response, Bodum argued that: (1) Meyer failed to provide sufficient evidence of an intent to induce infringement; (2) Bodum could not induce infringement because it believed in good faith that the Meyer patents are invalid; (3) Bodum could not be liable for inducement because no single third party could perform all the steps in the patented claims, not even Mr. Karvelis; and (4) even if Mr. Karvelis had performed all of the steps of the method claims, his acts could not be acts of “infringement” since he was acting under an implied license created by the umbrella of the parties’ litigation.

Two things are notable about the parties’ summary judgment filings. First, Meyer presented no evidence that anyone other than its own expert had directly “infringed” the ’087 and ’122 Patents. Second, both parties discussed what it meant to “provide a container” for frothing though, again, neither expressly sought construction of that term.

On February 11, 2009, the district court granted Meyer’s motion for partial summary judgment, finding that Bodum had induced infringement of certain claims in the ’087 and ’122 Patents by its sales of the Version 1 frothers.

Meyer then filed a second motion for partial summary judgment, this time arguing that Bodum’s sale of its Version 2 and 3 frothers both directly infringed and induced infringement of the ’122 Patent. The court granted summary judgment of direct infringement and inducement as to the Version 2 frothers, but found genuine
issues of material fact as to literal infringement with respect to the Version 3 frothers. …

…

Discussion

On appeal, Bodum argues that the district court erred when it … granted summary judgment of direct infringement and inducement of the asserted method claims, despite the lack of evidence that any one party—including Bodum—actually performed each step of the asserted claims … .

A. Infringement

The district court issued two separate decisions granting summary judgment that Bodum directly infringed and induced infringement of the patents-in-suit. First, with respect to Bodum’s Version 1 frothers, the court found that: (1) Bodum conceded direct infringement; and (2) whenever a Bodum customer uses its milk frother and follows the instructions contained therein, that customer directly infringes the patents-in-suit, and Bodum induces the same as a matter of law. Bodum moved the district court to clarify its decision, arguing that it could not be a direct infringer because it only practices the first step of the claim—“providing a container”—and its customers could not be direct infringers because, while they practice each of the other steps, they do not practice the “providing” step. The district court judge conducted a status hearing and explained to Bodum that:

I took a look at the box that contains this plunger. And everything that you have done is everything except hold the customer’s hand on the plunger. I mean you know, you have given the direct—you have got essentially a one purpose invention. And you have done everything, including the first step to practice the thing, because again all that you lack is putting your client’s hot hand on the plunger, because you instructed the customer, “Here is how you use the thing.”

Accordingly, the court denied Bodum’s motion to clarify.

The district court subsequently granted Meyer’s motion for summary judgment that Bodum’s sale of the Version 2 frothers infringe the claims of the ’122 Patent, finding that: (1) Bodum must have tested its products before putting them on the market; and (2) “[t]hough Meyer does not provide evidence of specific instances of direct infringement by Bodum’s customers, such proof is not required because *** Version 2 ‘necessarily infringes’ the patented method when operated as directed.”

We review the district court’s grant of summary judgment without deference, drawing all reasonable inferences in favor of the nonmoving party. King Pharm., Inc. v. Eon Labs., Inc., 616 F.3d 1267, 1273 (Fed. Cir. 2010). … Evaluating a district court decision granting summary judgment of infringement requires two steps: (1) claim construction; and (2) comparison of the properly construed claims to the accused product or process. Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009).

Where, as here, the asserted patent claims are method claims, the sale of a product, without more, does not infringe the patent. i4i Ltd. v. Microsoft Corp., 598 F.3d 831, 850 (Fed. Cir. 2010). Instead, direct infringement of a method claim re-
quires a showing that every step of the claimed method has been practiced. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009).

Under 35 U.S.C. § 271(b), a party who “actively induces infringement of a patent shall be liable as an infringer.” To prevail on an inducement claim, a patentee must establish that: (1) there has been direct infringement; (2) the defendant, with knowledge of the patent, actively and knowingly aided and abetted such direct infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc). It is well-established that a finding of direct infringement is a prerequisite to a finding of inducement. *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008) (“[A] finding of inducement requires a threshold finding of direct infringement.”).

On appeal, Bodum argues both that the district court assumed that acts of direct infringement occurred when there was no evidence in the record that they did and that the district court misapplied the law with respect to inducement in the context of method claims. According to Bodum, because there was no evidence that any single party, including Bodum itself, actually performed each step of the asserted method claims, there can be no finding of direct infringement or inducement. …

Meyer responds that: (1) as the district court held, Bodum waived its direct infringement argument with respect to Version 1; and (2) Bodum’s own witnesses admitted actual use of Bodum’s Version 1 and Version 2 frothers during testing of the frothers. …

For the reasons discussed below, we conclude that the district court erred in granting summary judgment of infringement with respect to both the Version 1 and Version 2 frothers because the record was inadequate to support such a conclusion as a matter of law. In reaching this conclusion … we find that, properly construed, each step of the method claims could be performed by a single user.

1. **Waiver**

First, we disagree with the district court’s finding that Bodum conceded direct infringement as to its Version 1 frother. In its initial motion seeking summary judgment, Meyer’s sole argument with respect to direct infringement was that “literal and direct infringement exists by one, such as Meyer’s expert, Albert Karvelis, when practicing the method prescribed in Bodum’s instructions while using Bodum’s accused milk frothers.” Meyer did not argue that anyone other than Mr. Karvelis practiced each step of the method claim by using Bodum’s Version 1 frother. Nor did Meyer offer evidence of or even argue that anyone at Bodum ever practiced every step of the method claim or that there was any known customer who did so.

In response, Bodum both rejected the notion that Mr. Karvelis’ actions could constitute acts of infringement and argued that no single person or entity—not even Mr. Karvelis—could perform all steps of the method claim because Bodum itself practiced the “providing a container” step, and only that step. Recognizing that induced infringement requires proof of both direct infringement and that the alleged inducer knowingly aided and abetted that direct infringement, Bodum argued that:
Meyer’s allegation of direct infringement is improper for at least the reason that, as drafted, no one party can directly infringe any of the independent method claims. Only Bodum performs the first step of each independent claim, the step of providing a container or housing associated with its Accused Products. The remaining steps are each performed only by Bodum’s customers. As a result there is no direct infringement and consequently, no inducement.

Given this language, we find that the district court erred in concluding that Bodum “raise[d] no defense to the argument that its products directly infringed the Meyer Patents.” In these circumstances, we agree with Bodum that no waiver occurred.

2. Claim Construction

Resolution of the parties’ dispute turns, in large part, on the construction of the term “providing” as it is used in the patent claims. ...

To ascertain the scope and meaning of the asserted claims, we look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence. Phillips v. AWH Corp., 415 F.3d 1303, 1315-17 (Fed. Cir. 2005) (en banc). As a general rule, a claim term is given the plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention. Id. at 1312-13.

Although claim construction begins with the language of the claims themselves, the claims “must be read in view of the specification, of which they are a part.” Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc). Indeed, the specification “is the single best guide to the meaning of a disputed term” and it “acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” Phillips, 415 F.3d at 1321 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). We have also recognized that dictionaries “are often useful to assist in understanding the commonly understood meaning of words.” Id. at 1322. As such, we have held that judges are free to rely on dictionary definitions when construing claims, “so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.” Id. at 1322-23 (quoting Vitronics, 90 F.3d at 1584 n. 6).

As noted, representative Claim 1 of the ‘087 Patent generally discloses four steps: (1) providing a container with a 2:1 height to diameter ratio; (2) pouring milk into the container; (3) introducing a plunger; and (4) pumping the plunger to aerate the liquid. The parties’ summary judgment arguments, and the district court’s ruling thereon, focused on the first step: “providing a container.” It is undisputed that the patents-in-suit do not explicitly define the term “providing.”

During claim construction, neither party asked the court to construe the term “providing.” Although claim construction is a question of law, we are generally hesitant to construe claim terms for the first time on appeal. Wavetronix v. EIS Elec. Integrated Sys., 573 F.3d 1343, 1355 (Fed. Cir. 2009). Under the circumstances of this case, however, we find it appropriate to do so. While the parties specifically ad-
dressed the meaning and scope of this term in their summary judgment briefing to the district court, the court did not formally construe the claim term because it found no reason to do so. Instead, the court found that Bodum could be liable for induced infringement even if it, and only it, performed the providing step because Bodum thereafter directed its customers on how to perform the remaining steps of the claim. Because the record is sufficiently developed to enable us to construe the term, and because the parties’ debate really focuses on the scope, rather than the meaning of the claim terms, we choose to address the question the trial court sidestepped.

In opposition to Meyer’s motion for summary judgment, Bodum supplied the following dictionary definition for the word “provide”: “1. To furnish; supply. 2. To make available; afford. 3. To set down as a stipulation. 4. Archaic: To make ready ahead of time; prepare.” *Am. Heritage College Dictionary* 1102 (3d ed. 2000). Bodum argued that, because it supplies, furnishes, and otherwise makes the accused products available for sale, it is the only party that can carry out the providing step. In its reply, Meyer agreed that providing should be given its common ordinary meaning, but argued that “there is no limitation in the claims on who does the ‘providing,’ and none exists. Bodum can do the providing or the end user completing the claimed method steps can do the providing. In either event, direct infringement occurs.”

In its decision granting summary judgment as to Bodum’s Version 1 frothers, the district court acknowledged Bodum’s proffered dictionary definition and its argument that, because an end user “cannot ‘provide’ the container as called for by the claims,” Bodum does not induce infringement. Rather than analyze the scope of the term “providing,” however, the district court found that, even under Bodum’s definition, Bodum’s argument fails because “it impermissibly distorts the fundamental concept of patent infringement.” Specifically, the court held that, “[w]hen any end user ‘uses’ a Bodum milk frother—a container—that has been ‘provided’ by Bodum, and in doing so follows Bodum’s instructions detailing the steps to be taken in such use of the frother *** it thus directly infringes the Meyer Patents.” Notably, however, nothing in the district court’s decision suggests that Bodum is the only party that can “provide” the container for use.

After careful review of the intrinsic evidence, we find that nothing in the claim language or the patent specification limits the “providing” step to a specific party. Under Bodum’s proffered dictionary definition, it is clear that Bodum “furnishes” or “supplies” the container by manufacturing and selling its milk frothers. It is also clear under that same definition, however, that anyone who takes a Bodum frother from the kitchen cabinet and places it on the counter before filling it with milk can satisfy the “providing” step. That person has undoubtedly made the container available for use and prepared it for frothing. Accordingly, we construe the term “providing” to mean “furnishing, supplying, making available, or preparing” and find that anyone—Bodum or the end user of its products—can satisfy the providing step. Given this construction, we find that the claims at issue here are drawn to actions that can be performed by a single party.
3. Direct Infringement

Having concluded that a single party is capable of infringing the patents-in-suit, we move to the parties’ arguments regarding infringement. We turn first to the issue of direct infringement. As noted, in its motion for summary judgment with respect to Bodum’s Version 1 frother, Meyer’s only evidence of direct infringement was the activities of Meyer’s own expert. On appeal, Bodum argues that Meyer did not introduce any evidence that either Bodum or its customers used the claimed method. Meyer responds that Bodum’s witnesses conceded use. Again, Meyer does not argue that there was evidence of customer infringement. For the reasons explained below, we agree with Bodum that the district court’s judgments of infringement as to both the Version 1 and Version 2 frothers suffer from the same deficiency: there was no evidence of direct infringement in the record.

As to the Version 1 frothers, the district court relied only on its conclusion that Bodum had conceded direct infringement, though the court never explained to whom that concession pertained. Because we find that Bodum made no such concession, Meyer points to no other evidence of direct infringement as to the Version 1 frothers, and we find none in the underlying summary judgment papers, we conclude that the trial court erred in finding direct infringement as a matter of law as to those frothers.

In its decision granting Meyer summary judgment with respect to the Version 2 frothers, the district court rejected Bodum’s argument that Meyer failed to prove direct infringement. Specifically, the court found it unbelievable that “an established company such as Bodum would have placed Version 2 and later Version 3 on the market for public sale, and would have kept those products on the market for substantial periods of time, without having first confirmed for itself that each product would perform its allotted task ***.” In other words, the court assumed that Bodum must have tested its products. Given this assumption, the court concluded that Bodum’s use of the ‘122 Patent method “has been established as a matter of law.”

We find it troubling that the district court based its direct infringement analysis on what it assumed happened, rather than on actual evidence of record. This assumption contradicts our well-established law that a patentee must prove infringement by a preponderance of the evidence. See Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 637 F.3d 1269, 1279 (Fed. Cir. 2011) (“Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence.”). And, by assuming testing without any evidence in the record, the court improperly drew an inference in favor of Meyer and against Bodum. Because factual inferences must be drawn in favor of the nonmoving party on summary judgment, we find that the district court’s decision cannot stand. See IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1429 (Fed. Cir. 2000).

For the first time on appeal, Meyer cites to deposition testimony from Bodum’s President, Thomas Perez, as evidence that Bodum used the claimed method in testing and developing its frothers. Specifically, Meyer points to Perez’s testimony that Bodum’s design team always tests each of its products. Bodum argues that Meyer’s reliance on this testimony is misplaced because the portions cited were neither sub-
mitted with the motions for summary judgment nor introduced at trial. In addition, Bodum points to the testimony of Jorgen Bodum, Bodum’s Chief Executive Officer (hereinafter referred to as “Jorgen”), that he conducts product development with his design team which consists of five people in Hong Kong and fifteen people in Switzerland. In other words, there is no evidence that Bodum used or tested its milk frother products in the United States.

We agree with Bodum that Meyer cannot for the first time on appeal introduce deposition testimony that was not before the district court when it was deciding the motions for summary judgment. And, given Jorgen’s trial testimony that Bodum’s product development team is located in Hong Kong and Switzerland, Meyer has not—at this stage—shown any instances of direct infringement in the United States. Because direct infringement of a method claim requires that each of the claimed steps are performed within the United States, the evidence of record is insufficient as a matter of law to support the court’s decision granting summary judgment. See NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1318 (Fed. Cir. 2005) (“We therefore hold that a process cannot be used ‘within’ the United States as required by section 271(a) unless each of the steps is performed within this country.”).

Based on the foregoing, we find that Meyer failed to point to specific instances of direct infringement and failed to offer any evidence that someone at Bodum used its Version 1 and Version 2 frothers. Accordingly, we find that there are genuine issues of material fact as to whether anyone at Bodum practiced each step of the asserted method claims.

We now turn to the trial court’s conclusion that Bodum intended that its customers would use the frothers to produce froth liquid and that the act of frothing thereafter would constitute direct infringement. While it may be true that Bodum’s customers may be characterized as direct infringers under our now-controlling construction of the providing step, Meyer never argued at the summary judgment stage that they were, and it does not make that argument here. Indeed, Meyer presented no evidence in support of its motion for summary judgment regarding either product sales or customer use; it relied only on Mr. Karvelis’ testing of the product. Judgment as a matter of law on such a sparse record is simply not appropriate.

Because we conclude that genuine issues of material fact remain, we reverse the district court’s grant of summary judgment with respect to Bodum’s Version 1 and Version 2 frothers and remand for further consideration … .

Dyk, Judge, concurring:

While I agree with and join the thorough majority opinion, in looking at this case from a broader perspective, one cannot help but conclude that this case is an example of what is wrong with our patent system. The patents essentially claim the use of a prior art French press coffee maker to froth milk. Instead of making coffee by using the plunger to separate coffee from coffee grounds, the plunger is depressed to froth milk. The idea of frothing cold milk by the use of aeration rather than steam is not new as reflected in the prior art Ghidini patent. Under the Supreme Court’s decision in KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398, 420
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(2007), and its predecessors, it would be reasonable to expect that the claims would have been rejected as obvious by the examiner, and, if not, that they would have been found obvious on summary judgment by the district court. But no such thing. The parties have spent hundreds of thousand of dollars and several years litigating this issue, and are invited by us to have another go of it in a second trial. Such wasteful litigation does not serve the interests of the inventorship community, nor does it fulfill the purposes of the patent system.

Export

Mueller’s Patent Law: 512-517

Union Carbide Chems. v. Shell Oil Co.
425 F.3d 1366 (Fed. Cir. 2005)

Rader, Judge:

The United States District Court for the District of Delaware granted final judgment to Union Carbide Chemicals & Plastics Technology Corporation and Union Carbide Corporation (collectively Union Carbide) after a jury found that Shell Oil Company, Shell Chemical Company, and CRI Catalyst Company (collectively Shell) infringed claim 4 of Union Carbide’s U.S. Patent No. 4,916,243 (the ’243 patent). Because substantial evidence supports the jury verdict, this court affirms that finding. However, because the district court improperly excluded Shell’s exportation of catalysts in its damages calculation, this court vacates the damage award and remands.

I.

In 1999, Shell filed a declaratory judgment action in ... Texas alleging that Union Carbide’s U.S. Patent No. 5,057,481 (the ’481 patent), U.S. Patent No. 4,908,343 (the ’343 patent), and the ’243 patent were invalid, unenforceable, and not infringed. One month later, Union Carbide sued Shell in ... Delaware alleging that six of Shell’s catalysts infringed those same patents. The two cases were consolidated for trial in Delaware. After a twelve day trial, a jury returned a verdict for Shell on issues of infringement and invalidity. Upon appeal, this court affirmed-in-part, reversed-in-part, and remanded.

In 2003, the district court held a second jury trial on the remanded issues involving only the ’243 patent. The jury returned a verdict finding that Shell’s S-880 and S-882 catalysts directly infringed claim 4 in the production of ethylene oxide (EO). The jury also found that Shell contributorily infringed claim 4 by selling its S-863, S-880 and S-882 catalysts to third parties. Accordingly, the jury awarded $112,198,893 in damages to Union Carbide. The trial court first adjusted that award to $111,212,665 after correcting for a clerical error and later to $153,615,774 for prejudgment interest. This damages award, however, did not account for Shell’s exportation of catalysts because the district court ruled in limine that 35 U.S.C. § 271(f) damages are not available for process claims, such as claim 4 of the ’243 patent. After considering post-trial motions from both parties, the district court entered a final judgment for Union Carbide and a permanent injunction against Shell, which it stayed pending Shell’s appeal to this court.

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Shell appeals the district court’s denial of its Judgment as a Matter of Law (JMOL) motions and the damages amount. Union Carbide cross-appeals the district court’s holding that 35 U.S.C. § 271(f) does not apply to process claims and the jury verdict finding that Shell’s infringement was not willful. …

II.

This court described the technology at issue in this case at length in [the prior appeal]. … In brief, the ’243 patent claims improved silver catalysts for the commercial production of EO. EO gas is used primarily in the industrial production of ethylene glycol, which is used, in turn, to produce polyester fiber, resin and film. Most of the EO produced each year is converted into monoethylene glycol (MEG). Union Carbide and its parent corporation, Dow Chemical, produce twenty-five percent of the MEG sold domestically. Shell is a direct competitor of Union Carbide and Dow Chemical in EO production and MEG sales.

Union Carbide’s proprietary process for EO production involves a highly exothermic reaction between ethylene and oxygen occurring between 250 and 300° C. ’243 patent, col. 12, l. 50 to col. 13, l. 30. Before 1971, the ordinary artisan in this field understood that a silver catalyst decreased the reaction temperature and increased reaction efficiency without consuming or altering the silver itself. However, no producer managed to increase the reaction efficiency beyond 65 percent. In 1971, scientists discovered that certain alkali metals in small amounts further promoted the efficiency of silver-catalyzed reactions. Union Carbide thus undertook considerable research on catalysts with silver and other alkali metals. This research led to the invention now claimed in the ’243 patent.

The ’243 patent claims a process for the production of EO with a greater decrease in the reaction temperature than processes using pure silver catalysts. Thus, this new process reduces the formation of oxygen and water byproducts and increases the efficiency of the reaction. ’243 patent, col. 8, ll. 39-55. Claim 4, the sole claim at issue in the present appeal, concerns a process involving a catalyst including silver, cesium and lithium. …

…

At trial, Union Carbide provided evidence showing that 58 samples of Shell catalysts met the comparison and characterizable limitations of claim 4. Specifically, Union Carbide’s expert witness, Professor Haller, tested samples sold by Shell commercially and catalysts that he produced by following recipes detailed in Shell’s internal documents. …

…”

IX.

On the cross appeal, Union Carbide asserts that the district court erred as a matter of law by ruling in limine that 35 U.S.C. § 271(f) “is not directed to process claims.” In doing so, the court prohibited Union Carbide from submitting evidence of Shell’s foreign sales for the purpose of recovering additional damages under 35 U.S.C. § 271(f)(2). This prohibition was in error.

Section 271(f) of title 35 is generally directed at the exportation, from the United States, of components of patented inventions. Specifically, § 271(f)(2) states:
Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f)(2) (emphasis added). This case again questions the meaning of the phrase “any component of a patented invention” in the statute. In other words, does this phrase apply to components used in the performance of patented process/method inventions? Eolas Techs. v. Microsoft Corp., 399 F.3d 1325, 1339 (Fed. Cir. 2005), recently answered this question in the affirmative, holding that every component of every form of invention deserves the protection of 35 U.S.C. § 271(f), i.e., that “components” and “patented inventions” under § 271(f) are not limited to physical machines. In Eolas, this court stated:

Section 271(f) refers to “components of a patented invention.” This statutory language uses the broad and inclusive term “patented invention.” Title 35, in the definitions section, defines “invention” to mean “invention or discovery”—again broad and inclusive terminology. 35 U.S.C. § 100(a). The next section in Title 35, section 101, explains that an invention includes “any new and useful process, machine, manufacture or composition of matter.”

Id. at 1338-39. Thus, as Eolas explained, the statute makes no distinction between patentable method/process inventions and other forms of patentable inventions.

Moreover, Eolas and this case featured similar facts. In Eolas, Microsoft exported a master computer disc with program code that caused a computer to perform various method steps. Thus, both this case and Eolas feature the exportation of a component (i.e., a computer disc with program code in Eolas and a catalyst in this case) used in the performance of a patented process or method (i.e., the method steps executed by the computer in response to the computer readable program code in Eolas and the commercial production of EO in this case). In that setting, Eolas applied § 271(f) to Microsoft’s exported component. Similarly, § 271(f) applies to Shell’s exportation of catalysts (i.e., a “component”) used in the commercial production of EO abroad (i.e., a “patented invention”).

In brief, because § 271(f) governs method/process inventions, Shell’s exportation of catalysts may result in liability under § 271(f). Accordingly, the district court abused its discretion in excluding Shell’s exportation of catalysts as part of its damages award. This court remands this case to the district court for additional findings on Shell’s potential liability under 35 U.S.C. § 271(f).
Microsoft Corp. v. AT&T Corp.

Ginsburg, Justice:

It is the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country. There is an exception. Section 271(f) of the Patent Act, adopted in 1984, provides that infringement does occur when one “supplies *** from the United States,” for “combination” abroad, a patented invention’s “components.” 35 U.S.C. § 271(f)(1). This case concerns the applicability of § 271(f) to computer software first sent from the United States to a foreign manufacturer on a master disk, or by electronic transmission, then copied by the foreign recipient for installation on computers made and sold abroad.

AT&T holds a patent on an apparatus for digitally encoding and compressing recorded speech. Microsoft’s Windows operating system, it is conceded, has the potential to infringe AT&T’s patent, because Windows incorporates software code that, when installed, enables a computer to process speech in the manner claimed by that patent. It bears emphasis, however, that uninstalled Windows software does not infringe AT&T’s patent any more than a computer standing alone does; instead, the patent is infringed only when a computer is loaded with Windows and is thereby rendered capable of performing as the patented speech processor. The question before us: Does Microsoft’s liability extend to computers made in another country when loaded with Windows software copied abroad from a master disk or electronic transmission dispatched by Microsoft from the United States? Our answer is “No.”

The master disk or electronic transmission Microsoft sends from the United States is never installed on any of the foreign-made computers in question. Instead, copies made abroad are used for installation. Because Microsoft does not export from the United States the copies actually installed, it does not “suppl[y] *** from the United States” “components” of the relevant computers, and therefore is not liable under § 271(f) as currently written.

Plausible arguments can be made for and against extending § 271(f) to the conduct charged in this case as infringing AT&T’s patent. Recognizing that § 271(f) is an exception to the general rule that our patent law does not apply extra-territorially, we resist giving the language in which Congress cast § 271(f) an expansive interpretation. Our decision leaves to Congress’ informed judgment any adjustment of § 271(f) it deems necessary or proper.

Our decision some 35 years ago in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), a case about a shrimp deveining machine, led Congress to enact § 271(f). In that case, Laitram, holder of a patent on the time-and-expensesaving machine, sued Deepsouth, manufacturer of an infringing deveiner. Deepsouth conceded that the Patent Act barred it from making and selling its deveining machine in the United States, but sought to salvage a portion of its business: Nothing in United States patent law, Deepsouth urged, stopped it from making in the United States the parts of its deveiner, as opposed to the machine it-
self, and selling those parts to foreign buyers for assembly and use abroad. *Id.* at 522-524. We agreed.

Interpreting our patent law as then written, we reiterated in *Deepsouth* that it was “not an infringement to make or use a patented product outside of the United States.” *Id.* at 527. *Deepsouth*’s foreign buyers did not infringe Laitram’s patent, we held, because they assembled and used the deveining machines outside the United States. *Deepsouth*, we therefore concluded, could not be charged with inducing or contributing to an infringement. *Id.* at 526-527. Nor could *Deepsouth* be held liable as a direct infringer, for it did not make, sell, or use the patented invention—the fully assembled deveining machine—within the United States. The parts of the machine were not themselves patented, we noted, hence export of those parts, unassembled, did not rank as an infringement of Laitram’s patent. *Id.* at 527-529.

Laitram had argued in *Deepsouth* that resistance to extension of the patent privilege to cover exported parts “derived from too narrow and technical an interpretation of the [Patent Act].” *Id.* at 529. Rejecting that argument, we referred to prior decisions holding that “a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.” *Id.* at 528. Congress’ codification of patent law, we said, signaled no intention to broaden the scope of the privilege. *Id.* at 530 (“When, as here, the Constitution is permissive, the sign of how far Congress has chosen to go can come only from Congress.”). And we again emphasized that

[our patent system makes no claim to extraterritorial effect; these acts of Congress do not, and were not intended to, operate beyond the limits of the United States; and we correspondingly reject the claims of others to such control over our markets.

*Id.* at 531 (quoting *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 195 (1857)). Absent “a clear congressional indication of intent,” we stated, courts had no warrant to stop the manufacture and sale of the parts of patented inventions for assembly and use abroad. 406 U.S. at 532.


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3 See also, e.g., S. Rep. No. 98-663, pp. 2-3 (1984) (describing § 271(f) as “a response to the Supreme Court’s 1972 *Deepsouth* decision which interpreted the patent law not to make it infringement where the final assembly and sale is abroad”); Section-by-Section Analysis of H.R. 6286, 130 Cong. Rec. 28069 (1984) (“This proposal responds to the United States Supreme Court decision in *Deepsouth*** concerning the need for a legislative solution to close a loophole in [the] patent law.”).
(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.


II

Windows is designed, authored, and tested at Microsoft’s Redmond, Washington, headquarters. Microsoft sells Windows to end users and computer manufacturers, both foreign and domestic. Purchasing manufacturers install the software onto the computers they sell. Microsoft sends to each of the foreign manufacturers a master version of Windows, either on a disk or via encrypted electronic transmission. The manufacturer uses the master version to generate copies. Those copies, not the master sent by Microsoft, are installed on the foreign manufacturer’s computers. Once assembly is complete, the foreign-made computers are sold to users abroad.4

AT&T’s patent (‘580 patent) is for an apparatus (as relevant here, a computer) capable of digitally encoding and compressing recorded speech. Windows, the parties agree, contains software that enables a computer to process speech in the manner claimed by the ‘580 patent. In 2001, AT&T filed an infringement suit in the United States District Court for the Southern District of New York, charging Microsoft with liability for domestic and foreign installations of Windows.

Neither Windows software (e.g., in a box on the shelf) nor a computer standing alone (i.e., without Windows installed) infringes AT&T’s patent. Infringement occurs only when Windows is installed on a computer, thereby rendering it capable of performing as the patented speech processor. Microsoft stipulated that by installing Windows on its own computers during the software development process, it directly infringed the ‘580 patent. Microsoft further acknowledged that by licensing copies of Windows to manufacturers of computers sold in the United States, it induced infringement of AT&T’s patent.

4 Microsoft also distributes Windows to foreign manufacturers indirectly, by sending a master version to an authorized foreign “replicator”; the replicator then makes copies and ships them to the manufacturers.
Microsoft denied, however, any liability based on the master disks and electronic transmissions it dispatched to foreign manufacturers, thus joining issue with AT&T. By sending Windows to foreign manufacturers, AT&T contended, Microsoft “supplie[d] *** from the United States,” for “combination” abroad, “components” of AT&T’s patented speech processor; accordingly, AT&T urged, Microsoft was liable under § 271(f). Microsoft responded that unincorporated software, because it is intangible information, cannot be typed a “component” of an invention under § 271(f). In any event, Microsoft urged, the foreign-generated copies of Windows actually installed abroad were not “supplie[d] *** from the United States.” Rejecting these responses, the District Court held Microsoft liable under § 271(f). On appeal, a divided panel of the Court of Appeals for the Federal Circuit affirmed. We granted certiorari and now reverse.

III

A

This case poses two questions: First, when, or in what form, does software qualify as a “component” under § 271(f)? Second, were “components” of the foreign-made computers involved in this case “supplie[d]” by Microsoft “from the United States”?7

As to the first question, no one in this litigation argues that software can never rank as a “component” under § 271(f). The parties disagree, however, over the stage at which software becomes a component. Software, the “set of instructions, known as code, that directs a computer to perform specified functions or operations,” Fantasy Sports Properties, Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1118 (Fed. Cir. 2002), can be conceptualized in (at least) two ways. One can speak of software in the abstract: the instructions themselves detached from any medium. (An analogy: The notes of Beethoven’s Ninth Symphony.) One can alternatively envision a tangible “copy” of software, the instructions encoded on a medium such as a CD-ROM. (Sheet music for Beethoven’s Ninth.) AT&T argues that software in the abstract, not simply a particular copy of software, qualifies as a “component” under § 271(f). Microsoft and the United States argue that only a copy of software, not software in the abstract, can be a component.

The significance of these diverse views becomes apparent when we turn to the second question: Were components of the foreign-made computers involved in this case “supplie[d]” by Microsoft “from the United States”? If the relevant components are the copies of Windows actually installed on the foreign computers, AT&T could not persuasively argue that those components, though generated abroad, were “supplie[d] *** from the United States” as § 271(f) requires for liability to attach.9

7 The record leaves unclear which paragraph of § 271(f) AT&T’s claim invokes. While there are differences between § 271(f)(1) and (f)(2), the parties do not suggest that those differences are outcome determinative. For clarity’s sake, we focus our analysis on the text of § 271(f)(1).

9 On this view of “component,” the copies of Windows on the master disks and electronic transmissions that Microsoft sent from the United States could not themselves serve as a basis for liability, because those copies were not installed on the for-
If, on the other hand, Windows in the abstract qualifies as a component within § 271(f)’s compass, it would not matter that the master copies of Windows software dispatched from the United States were not themselves installed abroad as working parts of the foreign computers.\(^{10}\)

With this explanation of the relationship between the two questions in view, we further consider the twin inquiries.

B

First, when, or in what form, does software become a “component” under § 271(f)? We construe § 271(f)’s terms “in accordance with [their] ordinary or natural meaning.” *FDIC v. Meyer*, 510 U.S. 471, 476 (1994). Section 271(f) applies to the supply abroad of the “components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components.” § 271(f)(1) (emphasis added). The provision thus applies only to “such components”\(^{11}\) as are combined to form the “patented invention” at issue. The patented invention here is AT&T’s speech-processing computer.

Until it is expressed as a computer-readable “copy,” e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable. It cannot be inserted into a CD-ROM drive or downloaded from the Internet; it cannot be installed or executed on a computer. Abstract software code is an idea without physical embodiment, and as such, it does not match § 271(f)’s categorization: “components” amenable to “combination.” Windows abstracted from a tangible copy no doubt is information—a detailed set of instructions—and thus might be compared to a blueprint (or anything containing design information, e.g., a schematic, template, or prototype). A blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component of that device. AT&T and its amici do not suggest otherwise. *Cf. Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117-19 (Fed. Cir. 2004) (transmission abroad of instructions for production of patented computer chips not covered by § 271(f)).

AT&T urges that software, at least when expressed as machine-readable object code, is distinguishable from design information presented in a blueprint. Software, unlike a blueprint, is “modular”; it is a stand-alone product developed and marketed “for use on many different types of computer hardware and in conjunction with

\(^{10}\) The Federal Circuit panel in this case, relying on that court’s prior decision in *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005), held that software qualifies as a component under § 271(f). We are unable to determine, however, whether the Federal Circuit panels regarded a component software in the abstract, or a copy of software.

\(^{11}\) “Component” is commonly defined as “a constituent part,” “element,” or “ingredient.” *Webster’s Third New International Dictionary of the English Language* 466 (1981).
many other types of software.” Software’s modularity persists even after installation; it can be updated or removed (deleted) without affecting the hardware on which it is installed. Software, unlike a blueprint, is also “dynamic.” After a device has been built according to a blueprint’s instructions, the blueprint’s work is done (as AT&T puts it, the blueprint’s instructions have been “exhausted”). Software’s instructions, in contrast, are contained in and continuously performed by a computer.

The distinctions advanced by AT&T do not persuade us to characterize software, uncoupled from a medium, as a combinable component. Blueprints too, or any design information for that matter, can be independently developed, bought, and sold. If the point of AT&T’s argument is that we do not see blueprints lining stores’ shelves, the same observation may be made about software in the abstract: What retailers sell, and consumers buy, are copies of software. Likewise, before software can be contained in and continuously performed by a computer, before it can be updated or deleted, an actual, physical copy of the software must be delivered by CD-ROM or some other means capable of interfacing with the computer.

Because it is so easy to encode software’s instructions onto a medium that can be read by a computer, AT&T intimates, that extra step should not play a decisive role under § 271(f). But the extra step is what renders the software a usable, combinable part of a computer; easy or not, the copy-producing step is essential. Moreover, many tools may be used easily and inexpensively to generate the parts of a device. A machine for making sprockets might be used by a manufacturer to produce tens of thousands of sprockets an hour. That does not make the machine a “component” of the tens of thousands of devices in which the sprockets are incorporated, at least not under any ordinary understanding of the term “component.” Congress, of course, might have included within § 271(f)’s compass, for example, not only combinable “components” of a patented invention, but also “information, instructions, or tools from which those components readily may be generated.” It did not. In sum, a copy of Windows, not Windows in the abstract, qualifies as a “component” under § 271(f).

The next question, has Microsoft “supplie[d] *** from the United States” components of the computers here involved? Under a conventional reading of § 271(f)’s text, the answer would be “No,” for the foreign-made copies of Windows actually installed on the computers were “supplie[d]” from places outside the United States. The Federal Circuit majority concluded, however, that “for software ‘components,’ the act of copying is subsumed in the act of ‘supplying.’” A master sent abroad, the majority observed, differs not at all from the exact copies, easily, inexpensively, and swiftly generated from the master; hence “sending a single copy

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13 We need not address whether software in the abstract, or any other intangible, can ever be a component under § 271(f). If an intangible method or process, for instance, qualifies as a “patented invention” under § 271(f) (a question as to which we express no opinion), the combinable components of that invention might be intangible as well. The invention before us, however, AT&T’s speech-processing computer, is a tangible thing.
abroad with the intent that it be replicated invokes § 271(f) liability for the foreign-made copies.”

Judge Rader, dissenting, noted that “supplying” is ordinarily understood to mean an activity separate and distinct from any subsequent “copying, replicating, or reproducing—in effect manufacturing.” He further observed: “The only true difference between making and supplying software components and physical components [of other patented inventions] is that copies of software components are easier to make and transport.” But nothing in § 271(f)’s text, Judge Rader maintained, renders ease of copying a relevant, no less decisive, factor in triggering liability for infringement. We agree.

Section 271(f) prohibits the supply of components “from the United States *** in such manner as to actively induce the combination of such components.” § 271(f)(1) (emphasis added). Under this formulation, the very components supplied from the United States, and not copies thereof, trigger § 271(f) liability when combined abroad to form the patented invention at issue. Here, as we have repeatedly noted, the copies of Windows actually installed on the foreign computers were not themselves supplied from the United States. Indeed, those copies did not exist until they were generated by third parties outside the United States. Copying software abroad, all might agree, is indeed easy and inexpensive. But the same could be said of other items: “Keys or machine parts might be copied from a master; chemical or biological substances might be created by reproduction; and paper products might be made by electronic copying and printing.” Brief for United States as Amicus Curiae 24. Section 271(f) contains no instruction to gauge when duplication is easy and cheap enough to deem a copy in fact made abroad nevertheless “supplied[ ][ ] *** from the United States.” The absence of anything addressing copying in the statutory text weighs against a judicial determination that replication abroad of a master dispatched from the United States “supplies” the foreign-made copies from the United States within the intendment of § 271(f).16

Any doubt that Microsoft’s conduct falls outside § 271(f)’s compass would be resolved by the presumption against extraterritoriality, on which we have already touched. The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law. The traditional understanding that our patent law “operate[s] only domestically and do[es] not extend to foreign activities,” Fisch & Allen at 559, is embedded in the Patent Act itself, which

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16 Our analysis, while focusing on § 271(f)(1), is equally applicable to § 271(f)(2). While the two paragraphs differ, among other things, on the quantity of components that must be “supplied[d] *** from the United States” for liability to attach, that distinction does not affect our analysis. Paragraph (2), like (1), covers only a “component” amenable to “combination.” Paragraph (2), like (1), encompasses only the “[s]uppl[y] *** from the United States” of “such [a] component” as will itself “be combined outside of the United States.” It is thus unsurprising that AT&T does not join the dissent in suggesting that the outcome might turn on whether we view the case under paragraph (1) or (2).
provides that a patent confers exclusive rights in an invention within the United States. 35 U.S.C. § 154(a)(1) (patentee’s rights over invention apply to manufacture, use, or sale “throughout the United States” and to importation “into the United States”). See Deepsouth, 406 U.S. at 531 (“Our patent system makes no claim to extraterritorial effect”; our legislation “d[oes] not, and [was] not intended to, operate beyond the limits of the United States, and we correspondingly reject the claims of others to such control over our markets.” (quoting Brown, 60 U.S. (19 How.) at 195)).

As a principle of general application, moreover, we have stated that courts should “assume that legislators take account of the legitimate sovereign interests of other nations when they write American laws.” F. Hoffmann-La Roche Ltd. v. Empagran S.A., 542 U.S. 155, 164 (2004); see EEOC v. Arabian American Oil Co., 499 U.S. 244, 248 (1991). Thus, as the United States accurately conveyed in this case: “Foreign conduct is [generally] the domain of foreign law,” and in the area here involved, in particular, foreign law “may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions.” Brief for United States as Amicus Curiae 28. Applied to this case, the presumption tugs strongly against construction of § 271(f) to encompass as a “component” not only a physical copy of software, but also software’s intangible code, and to render “supplie[d] *** from the United States” not only exported copies of software, but also duplicates made abroad.

AT&T argues that the presumption is inapplicable because Congress enacted § 271(f) specifically to extend the reach of United States patent law to cover certain activity abroad. But as this Court has explained, “the presumption is not defeated *** just because [a statute] specifically addresses [an] issue of extraterritorial application,” Smith v. United States, 507 U.S. 197, 204 (1993); it remains instructive in determining the extent of the statutory exception. See Empagran, 542 U.S. at 161-62, 164-65; Smith, 507 U.S. at 204.

AT&T alternately contends that the presumption holds no sway here given that § 271(f), by its terms, applies only to domestic conduct, i.e., to the supply of a patented invention’s components “from the United States.” § 271(f)(1). AT&T’s reading, however, “converts a single act of supply from the United States into a springboard for liability each time a copy of the software is subsequently made [abroad] and combined with computer hardware [abroad] for sale [abroad.]” Brief for United States as Amicus Curiae 29. In short, foreign law alone, not United States law, currently governs the manufacture and sale of components of patented inventions in foreign countries. If AT&T desires to prevent copying in foreign countries, its remedy today lies in obtaining and enforcing foreign patents. See Deepsouth, 406 U.S. at 531.17

17 AT&T has secured patents for its speech processor in Canada, France, Germany, Great Britain, Japan, and Sweden. AT&T and its amici do not relate what protections and remedies are, or are not, available under these foreign regimes.
IV

AT&T urges that reading § 271(f) to cover only those copies of software actually dispatched from the United States creates a “loophole” for software makers. Liability for infringing a United States patent could be avoided, as Microsoft’s practice shows, by an easily arranged circumvention: Instead of making installation copies of software in the United States, the copies can be made abroad, swiftly and at small cost, by generating them from a master supplied from the United States. The Federal Circuit majority found AT&T’s plea compelling:

Were we to hold that Microsoft’s supply by exportation of the master versions of the Windows software—specifically for the purpose of foreign replication—avoids infringement, we would be subverting the remedial nature of § 271(f), permitting a technical avoidance of the statute by ignoring the advances in a field of technology—and its associated industry practices—that developed after the enactment of § 271(f). *** Section 271(f), if it is to remain effective, must therefore be interpreted in a manner that is appropriate to the nature of the technology at issue.

While the [Federal Circuit] majority’s concern is understandable, we are not persuaded that dynamic judicial interpretation of § 271(f) is in order. The “loophole,” in our judgment, is properly left for Congress to consider, and to close if it finds such action warranted.

There is no dispute, we note again, that § 271(f) is inapplicable to the export of design tools—blueprints, schematics, templates, and prototypes—all of which may provide the information required to construct and combine overseas the components of inventions patented under United States law. We have no license to attribute to Congress an unstated intention to place the information Microsoft dispatched from the United States in a separate category.

Section 271(f) was a direct response to a gap in our patent law revealed by this Court’s Deepsouth decision. The facts of that case were undeniably at the fore when § 271(f) was in the congressional hopper. In Deepsouth, the items exported were kits containing all the physical, readily assemblable parts of a shrimp deveining machine (not an intangible set of instructions), and those parts themselves (not foreign-made copies of them) would be combined abroad by foreign buyers. Having attended to the gap made evident in Deepsouth, Congress did not address other arguable gaps: Section 271(f) does not identify as an infringing act conduct in the United States that facilitates making a component of a patented invention outside the United States; nor does the provision check “suppl[ying] *** from the United States” information, instructions, or other materials needed to make copies abroad. Given that Congress did not home in on the loophole AT&T describes, and in view of the expanded extraterritorial thrust AT&T’s reading of § 271(f) entails, our precedent leads us to leave in Congress’ court the patent-protective determination AT&T seeks. Cf. Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417, 431 (1984) (“In a case like this, in which Congress has not plainly marked our course, we must be circumspect in construing the scope of rights created by a legislative enactment which never contemplated such a calculus of interests.”).
Congress is doubtless aware of the ease with which software (and other electronic media) can be copied, and has not left the matter untouched. In 1998, Congress addressed “the ease with which pirates could copy and distribute a copyrightable work in digital form.” Universal City Studios, Inc. v. Corley, 273 F.3d 429, 435 (2d Cir. 2001). The resulting measure, the Digital Millennium Copyright Act, 17 U.S.C. § 1201 et seq., “backed with legal sanctions the efforts of copyright owners to protect their works from piracy behind digital walls such as encryption codes or password protections.” Universal City Studios, 273 F.3d at 435. If the patent law is to be adjusted better “to account for the realities of software distribution,” the alteration should be made after focused legislative consideration, and not by the Judiciary forecasting Congress’ likely disposition.

...  

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.  
576 F.3d 1348 (Fed. Cir. 2009) (en banc in part)  

Lourie, Judge: 

Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively, “Cardiac” or “appellants”) appeal from the decision of the United States District Court for the Southern District of Indiana [regarding the alleged infringement of] claim 4 of U.S. Patent 4,407,288. ...  

St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, “St. Jude”) cross-appeal from the district court’s decision permitting damages under 35 U.S.C. § 271(f). The en banc court reverses the district court’s determination that 35 U.S.C. § 271(f) applies to method claims and hence permits damages in this case on devices exported where the claimed method is carried out in countries other than the United States (see Section C.2 of this opinion).  

Background  

This patent dispute concerning implantable cardioverter defibrillators (“ICDs”), has been before us on four previous occasions. ...  

ICDs are small devices that detect and correct abnormal heart rhythms that can be fatal if left untreated. The ICDs in this case work by administering electrical shocks to the heart, those shocks being calibrated to restore normal heart functioning. Implantable cardiac devices can be programmed to administer different types of electrical shocks, including pacing shocks (which are relatively low power shocks), defibrillation (relatively high power shocks), and cardioversion, the definition of which has been a source of dispute throughout the protracted litigation of this case.  

Cardiac owns various patents relating to cardiac defibrillators, including the ’288 patent. The ’288 patent claims a method of heart stimulation using an implantable heart stimulator that is capable of detecting heart arrhythmias, or irregular heart rhythms, and of being programmed to treat the arrhythmia through either single or multimode operation. Multimode operation allows a heart stimulator to respond to arrhythmias by applying first one type of shock and then, if unsuccessful, administering a second type of shock. ...
2. Section 271(f)

The court hears this section C(2) en banc. The district court, following our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), found that 35 U.S.C. § 271(f) applied to method claims and that St. Jude’s shipment of ICDs abroad could result in a violation of that section. On cross-appeal to this court, St. Jude challenged the court’s decision. The panel affirmed the court’s decision on the basis of Union Carbide. St. Jude filed a petition for rehearing en banc, which we granted, thus vacating the panel decision. The en banc court heard oral argument on this issue on May 29, 2009. For the reasons stated below, we reverse and hold that § 271(f) does not cover method claims and is therefore not implicated in this case.

In 2006, a panel of this court explicitly held that § 271(f) applied to method claims. In Union Carbide, the court was presented with a case in which a catalyst, which was necessary to perform a patented method for producing ethylene oxide, was exported from the United States. 425 F.3d 1366, 1369 (Fed. Cir. 2006). The court held that § 271(f) was applicable to the exportation of the catalyst and use of the patented method abroad. In doing so, the court referred to the catalyst as the “component” referred to in § 271(f). … Indeed, the court considered that the shipment of the chemical catalyst was an even stronger candidate for the application of § 271(f) than the shipment of master disks in Eolas because, unlike [the accused infringer in] Eolas, Shell used the shipped components directly in its process instead of using copies of the exported components. Id. at 1379. Thus, the court held that “because § 271(f) governs method/process inventions, Shell’s exportation of catalysts may result in liability” under that section. Id. at 1380.

The Supreme Court subsequently examined § 271(f) when it granted certiorari and reversed our decision in AT&T. 550 U.S. 437 (2007). The Court held that Microsoft did not supply combinable components of a patented invention when it shipped master disks abroad to be copied. Because the foreign-made copies of Windows that were installed on computers were supplied “from places outside of the United States,” the Court held that Microsoft had not supplied components from the United States. Id. at 452. The court reserved judgment on whether “an intangible method or process … qualifies as a ‘patented invention’ under § 271(f),” but noted that if so, the “combinable components of that invention might be intangible.” Id. at n.13. The Court sent a clear message that the territorial limits of patents should not be lightly breached. Id. at 454-56.
In construing the terms of § 271(f), we do so “in accordance with [their] ordinary or natural meaning.” *Id.* at 449 (alteration in original). Section 271(f)(1) provides that one who “supplies *** in or from the United States, all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components” shall be liable as an infringer. 35 U.S.C. § 271(f)(1). Section 271(f)(2) contains similar language.

Cardiac argues that the use of the term “patented invention” in 271(f) indicates Congress’s intent to include all classes of invention within that statute’s reach. Cardiac rightly notes that “invention” is defined in the U.S. Code to include “any new and useful process, machine, manufacture or composition of matter,” 35 U.S.C. § 101, and thus is broad enough to include method patents. However, examination of the statute before us is not quite so simple. While the isolated “patented invention” language in § 271(f) by itself might seem to extend to all inventions within the definition of “invention,” we cannot disregard all the other language of that section, which, as we shall demonstrate, makes it clear that it does not extend to method patents. We also cannot ignore the context of the statute and its legislative history, which lead us to the same conclusion, which is that § 271(f) does not encompass method patents.

In interpreting the terms of § 271(f), it is critical to recall what a “patented invention” consists of when method patents are at issue. We have noted “the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps.” *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002). Thus, a component of a tangible product, device, or apparatus is a tangible part of the product, device, or apparatus, whereas a component of a method or process is a step in that method or process. As we demonstrate herein, this fundamental distinction between claims to a product, device, or apparatus on one hand and claims to a process or method on the other, is critical to the meaning of the statute and dooms Cardiac’s argument on this issue.

Cardiac relies on the Supreme Court’s language in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), in which the Court stated: “Apparatus and method claims may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus.” *Id.* at 629. However, the Court’s language throughout the *Quanta* opinion is focused on the similarities between method and apparatus patents in the unique context of patent exhaustion. See, e.g., *id.* at 628 (noting that a method may be “embodied” in devices for purposes of a “sale”); *id.* at 629 (method patents may be “exhausted by the sale of an item”). Moreover, in an exhaustion context, which considers whether a patent owner has been fully compensated when a sale or license of his invention has occurred, it matters little whether the patent involved claims to a product (apparatus) or a method. If a patent owner sells or licenses a product, it is not unreasonable to hold that the patent owner has received his due compensation under the patent, whether it is a product or a method patent. Thus, as the Supreme Court stated, for purposes of exhaustion, it may “be difficult to distinguish the process from the function of the
apparatus.” *Id.* The Supreme Court’s statement in an exhaustion context has no application here.

Our precedents draw a clear distinction between method and apparatus claims for purposes of infringement liability, which is what § 271 is directed to. *See, e.g., Joy Tech.*, 6 F.3d at 773-75 (stating that method claims are infringed only by practicing the steps of the method). Section 271(f) “applies only to ‘such components’ as are combined to form the ‘patented invention’ at issue.” *AT&T*, 550 U.S. at 449. “Component” is defined as “a constituent part,” “element,” or “ingredient.” *Webster’s Third New International Dictionary of the English Language* 466 (1981). As we have seen, the patented invention at issue when a method patent is implicated consists of a “series of acts or steps.” *In re Kollar*, 286 F.3d at 1332. The elements of a method are the steps that comprise the method. Thus, method patents do have “components,” *viz.*, the steps that comprise the method, and thus they meet that definitional requirement of § 271(f), but the steps are not the physical components used in performance of the method.

Cardiac disagrees that a component of a patented method is a step of that method. Instead, Cardiac urges us to adopt a definition of “component” that would encompass “the apparatus that performed the process.” That position is clearly contrary to the text of § 271(f). …

Another subsection of § 271 further undercuts Cardiac’s proposed definition of “component.” It is a “fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme,” *Davis v. Mich. Dept. of Treasury*, 489 U.S. 803, 809 (1989). Section 271(c) illustrates the contrasting treatment that § 271 gives to tangible inventions and method inventions and the meaning of the term “component.” Section 271(c) contrasts “a component of a patented machine, manufacture, combination, or composition” with a “material or apparatus for use in practicing a patented process.” 35 U.S.C. § 271(c). Congress clearly believed that a “component” was separate and distinct from a “material or apparatus for use in practicing a patented process.” Thus, a material or apparatus for use in practicing a patented process is not a component of that process. The components of the process are the steps of the process.

Although such patented methods do have components, as indicated, § 271(f) further requires that those components be “supplied.” That requirement eliminates method patents from § 271(f)’s reach. The ordinary meaning of “supply” is to “provide that which is required,” or “to furnish with *** supplies, provisions, or equipment.” *Webster’s Third New International Dictionary of the English Language* 2297 (1981). These meanings imply the transfer of a physical object. Supplying an intangible step is thus a physical impossibility, a position that not even Cardiac seems to dispute. …

Any ambiguity as to Congress’s intent in enacting § 271(f) is further resolved by the presumption against extraterritoriality. The Supreme Court took a narrow view of § 271(f) by stating that the presumption against extraterritoriality still applies to § 271(f), even though that section specifically extends the reach of U.S.
patent law in a limited manner. AT&T, 550 U.S. at 454-56. In light of the near complete absence of any Congressional intent to protect patented methods under § 271(f) and the explicit Congressional purpose of overruling Deepsouth’s holding, the presumption compels us not to extend the reach of § 271(f) to method patents.

In sum, the language of § 271(f), its legislative history, and the provision’s place in the overall statutory scheme all support the conclusion that § 271(f) does not apply to method patents. We therefore overrule, to the extent that it conflicts with our holding today, our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), as well as any implication in Eolas or other decisions that § 271(f) applies to method patents.

We now turn to the facts of this case. Cardiac alleges that St. Jude violates § 271(f) when it ships its ICDs outside of the United States. We disagree. Claim 4 of the ’288 patent is comprised of the steps of determining a heart condition, selecting cardioversion as the appropriate therapy, and executing a cardioverting shock. Cardiac does not allege that all of those steps are carried out in the United States with respect to certain of the ICDs. Moreover, it cannot allege that the steps of the method are supplied, a contradiction in terms. Rather, Cardiac alleges that St. Jude’s shipment of a device that is capable of performing the method is sufficient to fall within the scope of § 271(f). Although the ICD that St. Jude produces can be used to perform the steps of the method, as we have demonstrated, § 271(f) does not apply to method or process patents. As § 271(f) does not encompass devices that may be used to practice a patented method, St. Jude is therefore not liable for infringement of claim 4 of the ’288 patent under § 271(f) for ICDs exported abroad.

...
Prior to the '980 invention, hGH could be obtained for therapeutic use only by extracting it from the pituitary glands of human cadavers. Known recombinant DNA methods for producing hGH were deficient; they yielded not only the amino acid sequence of the protein, but also a “leader sequence” of additional amino acids at the beginning of the protein. In the natural synthesis of hGH, the leader sequence enables the protein to emerge from a pituitary cell after expression; the leader is then enzymatically removed. When the product is recombinantly expressed in a bacterial host, however, the leader is not removed and it renders the resulting product biologically inactive.

The invention claimed in the '980 patent solved this problem by providing a method for directly expressing a human growth hormone expression product without a leader sequence. The inventors started with complementary DNA (“cDNA”) encoding hGH and its leader sequence, and cleaved the cDNA encoding the leader sequence along with a portion of the codons encoding hGH to obtain a cDNA fragment containing hGH codons 24-191. Next, they synthesized a DNA fragment corresponding to the 23 missing codons plus a “start” codon, and fused that DNA fragment to the cDNA fragment. They inserted the resulting semi-synthetic gene into bacterial cells, which directly expressed a 192-amino acid product, met-hGH, consisting of the hGH molecule and one additional amino acid, methionine (“met”), coded for by the start codon. Met-hGH has essentially the same biological activity as the natural hormone, hGH. The '980 patent teaches that the amino acid, methionine, may be cleaved intracellularly in the bacterial host to produce a product that is identical to the natural hormone. Genentech sells met-hGH and hGH under the trademarks Protropin and Humatrope, respectively.

The second patent in suit, U.S. Patent 4,342,832, also assigned to Genentech, contains essentially the same disclosure as the '980 patent. The '832 patent claims, however, are directed to a method for constructing a replicable cloning vehicle (e.g., a plasmid) capable, in a microbial organism, of expressing a particular polypeptide (e.g., human growth hormone).

Like Genentech, BTG manufactures hGH by recombinant DNA techniques using a plasmid that contains a semi-synthetic gene engineered to express hGH without a leader sequence. BTG incorporates the plasmid into bacteria, which then express insoluble met-hGH in the form of biologically-inactive inclusion bodies. In a final step, BTG carries out a purification process that involves recovering soluble met-hGH free of inclusion bodies and cleaving the extra methionine residue to produce the final product, biologically-active hGH. BTG manufactures hGH in Israel, and it plans to import the product for sale in the United States under the trademark Bio-Tropin.

BTG filed an Investigational New Drug Application (“IND”) for hGH with the [FDA] in 1985. In 1986, BTG granted American Critical Care (“ACC”) an exclusive license under BTG’s patents and technology to use and sell hGH in the United States. ACC agreed to make payments to BTG, purchase hGH from BTG, and conduct clinical studies to obtain FDA approval for the product. In 1986, E.I. du Pont

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3 The '980 patent is a division of the '832 patent.
Miller’s Patent Cases


In January 1995, BTG sued Genentech in district court, seeking a declaratory judgment that the ’980 and ’832 patents are invalid, unenforceable, and not infringed by BTG. Genentech counterclaimed for infringement and moved for a preliminary injunction, arguing that BTG’s importation of hGH into the United States would infringe the ’980 and ’832 patents. After a hearing, the district court found that Genentech had established a reasonable likelihood of success on the merits of its counterclaim, since BTG’s process for producing hGH was within the literal scope of claim 2 of the ’980 patent, BTG’s process for making a plasmid was within the literal scope of claim 1 of the ’832 patent, and BTG’s asserted infringement defenses lacked merit. The court also found that Genentech would suffer irreparable harm absent a preliminary injunction and that the balance of the hardships and the public interest favored the grant of an injunction. The court therefore entered a preliminary injunction against BTG. This appeal followed. …

Discussion

A. Likelihood of Success on the Merits

The district court found it likely that BTG, by importing hGH into the United States, would infringe Genentech’s patent under the Process Patent Amendments Act of 1988 (“PPAA”), since BTG’s process for making hGH was within the literal scope of claim 2 of the ’980 patent and its process for constructing a replicable cloning vehicle (plasmid) was within the literal scope of claim 1 of the ’832 patent. See 35 U.S.C. § 271(g). The court rejected BTG’s several asserted defenses.

On appeal, BTG raises numerous challenges to the court’s determination of likelihood of success. As discussed below, each of these arguments lacks merit.

1. Infringement of the ’980 Patent

Claim 2 of the ’980 patent reads as follows:

2. A method for producing human growth hormone which method comprises [1] culturing bacterial transformants containing recombinant plasmids which will, in a transformant bacterium, express a gene for human growth hormone unaccompanied by the leader sequence of human growth

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hormone or other extraneous protein bound thereto, and [2] isolating and purifying said expressed human growth hormone.

BTG advances three non-infringement arguments with respect to claim 2. First, BTG contends that the product expressed by the bacterial host cells in its process is not “human growth hormone” as specified in claim 2, but rather is insoluble met-hGH in the form of biologically-inactive inclusion bodies. This argument is unpersuasive.

The ’980 specification defines the expression product produced by the claimed process as follows:

Of course, the expression product will in every case commence with the amino acid coded for by the translation start signal (in the case of ATG, f-methionine). One can expect this to be removed intracellularly, or in any event to leave the bioactivity of the ultimate product essentially unaffected. Col. 7, ll. 52-57. The specification therefore teaches that the expression product produced by the claimed process is met-hGH, which may or may not be converted to hGH depending on whether or not the extra methionine residue is cleaved intracellularly in the bacterial host. Thus, met-hGH is an expression product within the scope of the claimed process. See Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1368-69 (Fed. Cir. 1996) (“[W]e construe the claim term ‘human growth hormone’ [in claim 2 of the ’980 patent] to encompass both met-hGH and hGH.”).

Furthermore, at the preliminary injunction hearing there was expert testimony that an “inclusion body” is simply an aggregation of protein chains and that insoluble, biologically-inactive met-hGH that form inclusion bodies is still met-hGH. BTG points to no persuasive evidence to the contrary. Moreover, nothing in the claim language, specification, or prosecution history of the ’980 patent indicates that the expression product must be biologically active at the time of expression, before it has been isolated and purified. Rather, the district court found that recombinant expression products, whether formed as inclusion bodies or otherwise, are not biologically active until they are isolated from the bacterial host cells and purified. BTG has not shown any error in that conclusion. Thus, that the met-hGH formed during BTG’s process is not biologically active is neither surprising nor meaningful; BTG’s isolated and purified final product, hGH, is biologically active. We therefore reject BTG’s contention that its product is not “human growth hormone.”

Second, BTG contends that it uses its own patented purification process to recover soluble, biologically-active hGH from the inclusion bodies of met-hGH and that the ’980 patent does not disclose BTG’s unique purification process. Thus, BTG argues that its process does not involve “isolating and purifying” a human growth hormone expression product as required by claim 2. We disagree.

Claim 2 uses broad, generic language to define the steps of isolating and purifying the recombinantly produced hGH product. Nothing in the claim language, specification, or prosecution history suggests that the claim is limited to any particular technique for isolating and purifying the product. Further, BTG’s process meets these claim limitations. In its NDA, for example, BTG characterized its recovery of
soluble, biologically-active hGH from insoluble, biologically-inactive met-hGH in the form of inclusion bodies as a “purification” step. Similarly, at the preliminary injunction hearing there was expert testimony that these processes constitute a “purification” step within the meaning of claim 2. Thus, BTG’s process clearly involves “isolating and purifying [the] expressed human growth hormone,” as generically defined in claim 2. That BTG patented its unique purification method is irrelevant: “[T]he existence of one’s own patent does not constitute a defense to infringement of someone else’s patent. It is elementary that a patent grants only the right to exclude others and confers no right on its holder to make, use, or sell.” Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 879 n.4 (Fed. Cir. 1991).

Third, BTG argues that, assuming its process falls within the literal scope of claim 2, it “materially changes” the product made by the patented process, met-hGH, into hGH before importing the product into the United States. Thus, BTG contends that its importation of hGH into the United States would not be an act of infringement under 35 U.S.C. § 271(g).5 We disagree. This argument is based on an assumption that met-hGH is the only “product which is made by [the] process patented in the United States” under § 271(g). However, as indicated above, the production of hGH must also be considered to be within the literal scope of claim 2. See Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1369-70 (Fed. Cir. 1996).6 Thus, BTG’s imported product (hGH) is within the scope of claim 2. BTG therefore cannot maintain that the “materially changed” exception to infringement applies, because the product made by the patented process is not changed at all, let alone “materially changed.” The “materially changed” exception of § 271(g) requires, at a minimum, that there be a real difference between the product imported, offered for sale, sold, or used in the United States and the products produced by the patented process. If claim 2 were limited to a method for producing met-hGH, then we would have to determine whether BTG’s conversion of met-hGH to hGH produced a “materially changed” product. But claim 2 is not so limited and thus BTG’s argument lacks merit.

5 Section 271(g) provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. *** A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g) (emphasis added).

6 An hGH product could be produced by the claimed process by expressing met-hGH followed by intracellular cleavage of the extra methionine residue in the bacterial host, as taught in the ’980 specification, and then isolating and purifying the final product.
We therefore conclude that BTG has not shown that the district court clearly erred in finding that Genentech established a likelihood of success in proving literal infringement of claim 2 of the '980 patent. See Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282 (Fed. Cir. 1986) (literal infringement is established when every limitation of the patent claim is met in the accused device or process).

2. Infringement of the '832 Patent

With respect to claim 1 of the '832 patent, directed to a method of constructing a replicable cloning vehicle (e.g., a plasmid), BTG argues that it does not infringe because it only constructed the plasmid once, in Israel in 1983, before enactment of § 271(g). BTG contends that the district court erred in retroactively applying § 271(g) to conduct that was not an act of infringement when it occurred. We disagree.

Infringement under § 271(g) does not consist of the making of a product by a process patented in the United States; it is the importation, offer to sell, sale, or use of a product made by such process. Liability arises if “the importation, sale, offer to sell, or use of the product occurs during the term of such process patent.” § 271(g). BTG clearly intends to import and sell hGH in the United States during the term of the '832 patent. This meets the statutory requirement and does not amount to a retroactive imposition of liability.

Furthermore, the PPAA provides that it “shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.” Process Patent Amendments Act of 1988, § 9006(a), 102 Stat. 1107, 1567. Again, because BTG plans to make and import hGH after the effective date of the PPAA (and during the term of the '832 patent), there is no merit to BTG’s contention that the district court retroactively imposed liability on BTG.

The more difficult question is whether hGH is “a product which is made by a process patented in the United States,” even though claim 1 of the '832 patent is directed to a method for producing a replicable cloning vehicle (e.g., a plasmid), not hGH. The statute does not directly answer this question, because it only defines, at least in part, what products “will *** not be considered” to have been “made by” a patented process, namely, those that have been “materially changed by subsequent processes” or that have become “a trivial and nonessential component of another product.” § 271(g) (emphasis added). The statute does not specify what products will be considered to have been “made by” the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity to the product of the patented process on a case-by-case basis. See S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987) (“Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis.”); id. at 49 (“The Committee expects the courts to exercise careful judgment in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways.”).

Here, the district court held that hGH is a product that is “made by” the '832 patented process under § 271(g). In so holding, the court relied on the fact that BTG uses the claimed process of making a replicable cloning vehicle as an essential
part of an overall process for producing hGH. The court also relied on the legislative history of the PPAA, particularly the Senate Report, which states:

In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vector containing the DNA molecule is, in turn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still undergoing expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the polypeptide product will be considered to have been made by the patented process.


There is little doubt that the plasmid product of the claimed process and hGH are entirely different materials, one being more than materially changed in relation to the other. hGH is not a mere modification of the plasmid. However, the above excerpt from the legislative history of the PPAA indicates the correctness of the district court’s analysis. The legislative history precisely anticipated this fact situation and indicated Congress’s intent that infringement of a process for making a plasmid is not to be avoided by using it to express its intended protein. Moreover, the ’832 patent itself explicitly contemplates that the patented process will be used as part of an overall process for producing hGH; indeed, the patent discloses in detail how to make hGH by carrying out the claimed process and other necessary steps. Thus, it cannot be said as a matter of law that the production of hGH is too remote from the claimed process of making a replicable cloning vehicle. We therefore find no error in the court’s conclusion that hGH is a product that is “made by” the ’832 patented process.

Furthermore, since BTG has not shown that the district court erred in determining that BTG’s process for making a plasmid falls within the literal scope of claim 1 of the ’832 patent, the district court did not err in finding that Genentech established a likelihood of success in proving literal infringement of that claim. See Mannesmann Demag Corp., 793 F.2d at 1282.

BTG also contends that [the equitable defense of] laches bars Genentech’s infringement counterclaim. BTG asserts that in 1985 and 1986, Genentech knew that BTG had developed an hGH product and imported it into the United States for use in clinical trials. BTG contends that Genentech should have brought suit against BTG soon after it learned of this information. We disagree.
Prior to 1988, when § 271(g) became effective, importation of a product made abroad by a process patented in the United States was not an act of infringement. Thus, Genentech had no infringement claim against BTG before 1988. With no legal right to enforce, it cannot be said that Genentech unreasonably delayed during that time period.

Furthermore, even after § 271(g) was enacted in 1988, BTG was only importing hGH into the United States for use in clinical trials in support of its application for FDA approval. The district court found that this was non-infringing activity, see 35 U.S.C. § 271(e)(1), and that Genentech did not know before 1993 that BTG had imported hGH into the United States for purposes outside the scope of § 271(e)(1). BTG has not demonstrated error in these findings. Thus, we conclude that the court did not err in rejecting BTG’s laches defense.

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**Eli Lilly & Co. v. American Cyanamid Co.**

82 F.3d 1568 (Fed. Cir. 1996)

*Bryson, Judge:*

The ongoing struggle between “pioneer” drug manufacturers and generic drug distributors has once more come before our court. Eli Lilly and Company (Lilly), the “pioneer” drug manufacturer in this case, has filed suit for patent infringement against the appellees, who are involved in various ways in the distribution of a particular generic drug. Lilly sought a preliminary injunction, arguing that the importation and sale of the generic drug in this country infringed Lilly’s patent on a process for making a related compound. After a hearing, the [district court] denied Lilly’s request for a preliminary injunction. The court found that Lilly had failed to show that it was likely to prevail on the merits of its infringement claim and had failed to show that it would suffer irreparable harm in the absence of preliminary injunctive relief. Because Lilly has failed to overcome the substantial hurdle faced by a party seeking to overturn the denial of a preliminary injunction, we affirm.

I

The pharmaceutical product at issue in this case is a broad-spectrum antibiotic known as “cefaclor.” Cefaclor is a member of the class of cephalosporin antibiotics, all of which are based on the cephem nucleus. Although there are many different cephem compounds, only a few have utility as antibiotic drugs. Each of the known commercial methods for producing cefaclor requires the production of an intermediate cephem compound known as an enol. Once the desired enol cephem intermediate is obtained, it is then subjected to several processing steps in order to produce cefaclor.

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10 In 1988, § 271(e)(1) provided that “[i]t shall not be an act of infringement to make, use, or sell a patented invention *** solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” 35 U.S.C. § 271(e)(1).
Miller’s Patent Cases

A

Lilly developed cefaclor and patented it in 1975. Until recently, Lilly has been the exclusive manufacturer and distributor of cefaclor in this country. In addition to its product patent on cefaclor, Lilly obtained several patents covering different aspects of the manufacture of cefaclor, including processes for producing enol cepham intermediates. Many of those patents have now expired.

In 1995, Lilly purchased the patent at issue in this case, U.S. Patent No. 4,160,085. Claim 5 of that patent defines a method of producing enol cepham compounds, including what is called “compound 6,” an enol cepham similar to the one Lilly uses in its process for manufacturing cefaclor. The ’085 patent will expire on July 3, 1996.

Compound 6 differs from cefaclor in three respects. Although both compound 6 and cefaclor are based on the cepham nucleus, compound 6 has a hydroxy group at the 3-position on the cepham nucleus, a para-nitrobenzyl carboxylate ester at the 4-position, and a phenylacetyl group at the 7-position. Cefaclor has different groups at each of those positions: it has a chlorine atom at the 3-position, a free carboxyl group at the 4-position, and a phenylglycyl group at the 7-position. Each of those differences between compound 6 and cefaclor contributes to the effectiveness of cefaclor as an orally administered antibiotic drug. The free carboxyl group at the 4-position is believed important for antibacterial activity; the chlorine increases cefaclor’s antibiotic potency; and the phenylglycyl group enables cefaclor to be effective when taken orally.

To produce cefaclor from compound 6 requires four distinct steps. First, the hydroxy group is removed from the 3-position and is replaced by a chlorine atom, which results in the creation of “compound 7.” Second, compound 7 is subjected to a reaction that removes the phenylacetyl group at the 7-position, which results in the creation of “compound 8.” Third, a phenylglycyl group is added at the 7-position, which results in the creation of “compound 9.” Fourth, the para-nitrobenzyl carboxylate ester is removed from the 4-position, which results in the creation of cefaclor.

B

On April 27, 1995, defendants Zenith Laboratories and American Cyanamid Co. obtained permission from the Food & Drug Administration to distribute cefaclor in this country. Defendant Biocraft Laboratories had applied for FDA approval to manufacture and sell cefaclor in the United States but had not yet obtained that approval. All three have obtained large quantities of cefaclor that were manufactured in Italy by defendant Biochimica Opos, S.p.A.

On the same day that Zenith and Cyanamid obtained FDA approval to sell cefaclor in this country, Lilly obtained the rights to the ’085 patent and filed suit against Zenith, Cyanamid, Biocraft, and Opos. In its complaint, Lilly sought a declaration that the domestic defendants’ importation of cefaclor manufactured by Opos infringed Lilly’s rights under several patents, including the ’085 patent. Lilly also requested a preliminary injunction, based on the alleged infringement of claim 5
of the '085 patent, to bar the defendants from importing or inducing the importation of cefaclor manufactured by Opos.

The district court held a three-day hearing on the motion for a preliminary injunction. Following the hearing, the court denied the motion in a comprehensive opinion. The court devoted most of its attention to the question whether Lilly had met its burden of showing that it was likely to prevail on the merits of its claim that the defendants were liable for infringing claim 5 of the '085 patent.

Based on the evidence presented at the hearing, the district court concluded that Lilly had shown that it was likely to prevail on the issue of the validity of the '085 patent. With respect to the infringement issue, however, the court held that Lilly had not met its burden of showing that it was likely to prevail.

The district court correctly framed the issue as whether, under the Process Patent Amendments Act of 1988, the importers of cefaclor infringed claim 5 of the '085 patent, which granted U.S. patent protection to the process that Opos used to make compound 6. The Process Patent Amendments Act makes it an act of infringement to import, sell, offer to sell, or use in this country a product that was made abroad by a process protected by a U.S. patent. 35 U.S.C. § 271(g). The Act, however, does not apply if the product made by the patented process is “materially changed by subsequent processes” before it is imported. 35 U.S.C. § 271(g)(1).

The district court found that compound 6 and cefaclor differ significantly in their structure and properties, including their biological activity. Citing the Senate Report on the Process Patent Amendments Act, the district court found that, because the processing steps necessary to convert compound 6 to cefaclor “change the physical or chemical properties of the product in a manner which changes the basic utility of the product,” (citing S. Rep. No. 83, 100th Cong., 1st Sess. 50 (1987)), Lilly was not likely to succeed on its claim that the defendants infringed Lilly’s rights under claim 5 of the '085 patent by importing and selling cefaclor.

The district court also found that Lilly had failed to prove that it would suffer irreparable harm in the absence of a preliminary injunction. … [T]he court was not persuaded by Lilly’s arguments that it faced irreparable economic injury if it were not granted immediate equitable relief. Under the circumstances of this case, the district court found that an award of money damages would be an adequate remedy in the event that Lilly ultimately proves that the importation of cefaclor made by the Opos process infringes the '085 patent. In light of Lilly’s failure to establish either a likelihood of success on the merits or irreparable harm, the court found it unnecessary to articulate findings regarding the other factors bearing on the propriety of preliminary injunctive relief—the balance of the hardships and the effect of the court’s action on the public interest.

II

The Process Patent Amendments Act of 1988 was enacted to close a perceived loophole in the statutory scheme for protecting owners of United States patents. Prior to the enactment of the 1988 statute, a patentee holding a process patent could sue for infringement if others used the process in this country, but had no cause of action if such persons used the patented process abroad to manufacture
products, and then imported, used, or sold the products in this country. In that setting, the process patent owner’s only legal recourse was to seek an exclusion order for such products from the International Trade Commission under section 337a of the Tariff Act of 1930, 19 U.S.C. § 1337a. By enacting the Process Patent Amendments Act, the principal portion of which is codified as 35 U.S.C. § 271(g), Congress changed the law by making it an act of infringement to import into the United States, or to sell or use within the United States “a product which is made by a process patented in the United States *** if the importation, sale, or use of the product occurs during the term of such process patent.”

A concern raised during Congress’s consideration of the process patent legislation was whether and to what extent the new legislation would affect products other than the direct and unaltered products of patented processes—that is, whether the new statute would apply when a product was produced abroad by a patented process but then modified or incorporated into other products before being imported into this country. Congress addressed that issue by providing that a product that is “made by” a patented process within the meaning of the statute “will *** not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.” 35 U.S.C. § 271(g).

That language, unfortunately, is not very precise. Whether the product of a patented process is a “trivial and nonessential component” of another product is necessarily a question of degree. Even less well defined is the question whether the product of a patented process has been “materially changed” before its importation into this country. While applying that statutory language may be relatively easy in extreme cases, it is not at all easy in a closer case such as this one.

A

Lilly argues that the “materially changed” clause of section 271(g) must be construed in light of its underlying purpose, which is to protect the economic value of U.S. process patents to their owners. Prior to the enactment of the Process Patent Amendments Act, the value of a U.S. process patent could be undermined by a manufacturer who used the process abroad and then imported the product into this country. Because the purpose of the process patent legislation was to protect against such subversion of protected economic rights, Lilly argues that the statute should be read to apply to any such scheme that undercuts the commercial value of a U.S. process patent. In Lilly’s view, the product of a patented process therefore should not be considered “materially changed” if the principal commercial use of that product lies in its conversion into the product that is the subject of the infringement charge. Because cefaclor is the only product of compound 6 that is sold in the United States market, Lilly argues, the change in compound 6 that results in cefaclor—no matter how significant as a matter of chemical properties or molecular structure—is not a “material change” for purposes of section 271(g).

Although we are not prepared to embrace Lilly’s argument, we acknowledge that it has considerable appeal. Congress was concerned with the problem of the overseas use of patented processes followed by the importation of the products of those processes, and a grudging construction of the statute could significantly limit
the statute’s effectiveness in addressing the problem Congress targeted. That is especially true with respect to chemical products, as to which simple, routine reactions can often produce dramatic changes in the products’ structure and properties.

Nonetheless, while the general purpose of the statute informs the construction of the language Congress chose, purpose cannot displace language, and we cannot stretch the term “materially changed” as far as Lilly’s argument would require. The problem is that the language of the statute refers to changes in the product; the statute permits the importation of an item that is derived from a product made by a patented process as long as that product is “materially changed” in the course of its conversion into the imported item. The reference to a “changed” product is very hard to square with Lilly’s proposed test, which turns on the quite different question of whether the use or sale of the imported item impairs the economic value of the process patent.

The facts of this case demonstrate how far Lilly’s test strays from the statutory text. While Lilly notes that there are only four steps between compound 6 and cefaclor, and that all four steps involve relatively routine chemical reactions, Lilly does not suggest any limiting principle based on the structure of the intermediate product or the nature of the steps necessary to produce the imported product. Thus, even if there were ten complex chemical reactions that separated compound 6 from cefaclor, Lilly’s test would characterize the two compounds as not “materially” different as long as the primary commercial use of compound 6 in this country was to produce cefaclor.

Besides not responding to the natural meaning of the term “changed,” Lilly’s construction of the “materially changed” clause would create a curious anomaly. Lilly’s value-based construction of the clause turns in large measure on Lilly’s contention that the only commercial use for compound 6 in this country is to produce cefaclor; that is, Lilly views compound 6 and cefaclor as essentially the same product because compound 6 has no commercial use in the U.S. market except to produce cefaclor. Under that approach, however, the question whether compound 6 was “materially changed” in the course of its conversion to cefaclor would depend on whether and to what extent other derivative products of compound 6 are marketed in this country. Thus, under Lilly’s theory compound 6 would become materially different from cefaclor if and when compound 6 came to have other commercial uses in the United States, even though the respective structures and properties of the two compounds remained unchanged.

That is asking the statutory language to do too much work. We cannot accept the argument that the question whether one compound is “materially changed” in the course of its conversion into another depends on whether there are other products of the first compound that have economic value. We therefore do not adopt Lilly’s proposed construction of section 271(g). We look instead to the substantiality of the change between the product of the patented process and the product that is being imported.

In the chemical context, a “material” change in a compound is most naturally viewed as a significant change in the compound’s structure and properties. Without attempting to define with precision what classes of changes would be material and
what would not, we share the district court’s view that a change in chemical structure and properties as significant as the change between compound 6 and cefaclor cannot lightly be dismissed as immaterial. Although compound 6 and cefaclor share the basic cephem nucleus, which is the ultimate source of the antibiotic potential of all cephalosporins, the cephem nucleus is common to thousands of compounds, many of which have antibiotic activity, and many of which are dramatically different from others within the cephem family. Beyond the cephem nucleus that they have in common, compound 6 and cefaclor are different in four important structural respects, corresponding to the four discrete chemical steps between the two compounds. While the addition or removal of a protective group, standing alone, might not be sufficient to constitute a “material change” between two compounds (even though it could dramatically affect certain of their properties), the conversion process between compound 6 and cefaclor involves considerably more than the removal of a protective group. We therefore conclude that the statutory text of § 271(g) does not support Lilly’s contention that it is likely to prevail on the merits of its infringement claim.

B

In aid of their differing approaches to the issue of statutory construction, both sides in this dispute seek support for their positions in the legislative history of the 1988 statute. As is often the case, there is something in the legislative history for each side. On Lilly’s side, for example, are characterizations of the legislation as creating process patent protection that is “meaningful and not easily evaded,” H.R. Rep. No. 60, 100th Cong., 1st Sess. 13 (1987), and as excluding products only if they “cease to have a reasonable nexus with the patented process,” S. Rep. No. 83, 100th Cong., 1st Sess. 36 (1987). On the other side are directions for applying the statute to chemical intermediates—directions that suggest a narrower construction of the statute than Lilly proposes. On balance, while we do not find the legislative history dispositive, we conclude that it does not unequivocally favor Lilly’s position and thus does not raise doubts about the district court’s statutory analysis as applied to the facts of this case.

...
terial and minor later steps such as salt formation or removal of protective [groups] should not be construed in such a way that importation of the final product of that added step would not be an infringement.” *Id.* at 71. Other interest groups likewise offered support for the proposed limiting language, subject to similar qualifications. *See id.* at 63 (statement of the Intellectual Property Owners, Inc.); *id.* at 186 (statement of the American Intellectual Property Law Association).

The following year, the Administration again suggested adding the term “directly” to the proposed statute, this time in a hearing before a House committee. See Intellectual Property and Trade: Hearings before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the H. Comm. on the Judiciary, 99th Cong., 2d Sess. 58-59 (1986). The National Association of Manufacturers (NAM) agreed that the scope of process patent protection should be limited, but regarded the word “directly” as too restrictive; instead, the NAM suggested that the statute “not apply to products materially changed chemically by subsequent steps or processes from the product resulting from the patented process.” *Id.* at 275-76 (emphasis in original). That language, according to the NAM representative, would cover the case of “a chemical intermediate made abroad by a patented process,” but then “subjected to a common chemical reaction” and converted into “a salt or amino-derivative.” *Id.* at 275; *see also id.* at 280.

The drafters of subsequent process patent bills embraced the Administration’s suggestion to restrict the scope of the statute, but they did so by using the language suggested by the NAM. Thus, the term “materially changed” was adopted to exclude from the reach of the proposed statute those products that were significantly altered before their importation.

The House report on the 1986 version of the process patent legislation was the first committee report to discuss the meaning of the “materially changed” clause. It explained that if the patented process is for chemical X, and “subsequent modifications change the basic structure of chemical X so that a clearly different chemical Y results, the connection between the patented process and the product, chemical Y, is broken.” H.R. Rep. No. 807, 99th Cong., 2d Sess. 21 (1986). The report noted, however, that chemical X would not be “materially changed” within the meaning of the statute if the subsequent modifications of chemical X were only “trivial or conventional in nature” such as “modifications which result in the formation of simple derivatives, including salts or esters, or the removal of impurities,” or if the subsequent processing steps “only change [the] shape, size or form” of the product, such as by being diluted or put in tablet form. *Id.* at 21-22.

Efforts to enact process patent legislation continued the following year; those efforts ultimately bore fruit in 1988 with the enactment of the Process Patent Amendments Act. Although several persons during the 1987 Senate hearings called attention to the need to clarify the “materially changed” clause in light of the difficulty of applying it to chemical intermediates, see Process Patent Legislation: Hearing on S. 568, S. 573, and S. 635 before the Subcomm. on Patents, Copyrights & Trademarks of the S. Comm. on the Judiciary, 100th Cong., 1st Sess. 114 (1987) (statement on behalf of the Intellectual Property Owners, Inc.); *id.* at 146,
the bills considered during 1987 and 1988 continued to employ the prior language without modification.

The pertinent portion of the 1987 House report on the process patent bill was identical to the portion of the 1986 House report summarized above, except for some new material that was inserted into one paragraph of the 1987 report. The new material appears to have been intended to express the notion that, under certain circumstances, significant changes in the properties or structure of a chemical product do not render the product “materially changed” within the meaning of the statutory language. The principal portion of the added matter explained that a hypothetical chemical product, chemical X, is not “materially changed” if

chemical X is an important intermediate product, such as a polymer, which can materially be changed into an end product, albeit by trivial or conventional processes. In this respect, a product will be considered made by the patented process, regardless of any subsequent changes, if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging the commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.


The inserted language is not easy to interpret, in part because it purports to identify some products that can “materially be changed” without being “materially changed.” In any event, however, the inserted language appears not to apply to the present case, as it seems to contemplate that when an intermediate that is the product of a patented process undergoes significant changes in the course of conversion into an end product, the end product will be deemed to be made by the patented process if (and only if) it would not be commercially feasible to make the end product other than by using the patented process. In this case, Lilly concedes that it is both possible and commercially viable to make cefaclor by methods that do not include the process defined by claim 5 of the '085 patent. Therefore, even if the explanatory language from the 1987 House report were accorded equal status with the language of the statute itself, the explanatory language would not require that § 271(g) be read to reach the defendants’ conduct in this case.

Lilly seizes on the statement in the House report that suggests that a change in “the basic structure” of the intermediate is necessary in order to break “the connection between the patented process and the [final, imported] product.” H.R. Rep. No. 60 at 13. Because both compound 6 and cefaclor share the core cephem nucleus, Lilly contends that the process of converting compound 6 to cefaclor does not alter the “basic structure” of compound 6, and that compound 6 is therefore not “materially changed” by the process of converting it into cefaclor.

While Lilly’s argument on this point cannot be lightly dismissed, we do not think the use of the term “basic structure” in the House report limits the “materially changed” clause, as applied to a cephem compound, to a change that alters the core cephem nucleus. If adopted, Lilly’s argument would mean that there would never be a “material change” resulting from the conversion of one cephem compound to another. Lilly’s argument would also leave open the question whether even a change in the cephem nucleus would be sufficiently “basic” if, for example, the initial and
end products both contained the beta lactam ring, which is one of the components of the cephalosporin nucleus, and thus were members of the beta lactam “superfamily” of compounds. The effect of Lilly’s construction of § 271(g)(1), both within the family of cephem compounds and within other families of compounds that are based on a common nucleus, would be sweeping. Absent clearer congressional direction, we decline to adopt so broad a principle. We therefore decline Lilly’s invitation to find the answer to this case in the House report’s reference to changes in the “basic structure” of chemical intermediates.

Like the House report, the 1987 Senate report contains a detailed elaboration on the statutory term “material change.” In fact, the Senate report contains what may best be described as a detailed set of instructions to courts called on to construe that term as it applies to particular fields of technology. The report noted that many foreign patent statutes extending process patent protection to a product require that the product in question be made “directly” from the patented process and suggested that the term “materially changed” in section 271(g) was intended to embody a similar but somewhat broader scope of protection; as the Senate Committee explained, the term “directly” was not used, because it might have been read to “exempt too many products that have been altered in insignificant ways after manufacture by the patented process.” S. Rep. No. 83, 100th Cong., 1st Sess. 49 (1987).

Acknowledging that the task of determining whether a product was “materially changed” prior to its importation would ultimately be left to the courts, the Committee then set out a “two-phased test” to “give the courts Congressional guidance in what may be a difficult determination.” S. Rep. No. 83 at 50. The first part of the test restated the test set forth in the House report, i.e., that a product “will be considered made by the patented process *** if it would not be possible or commercially viable to make that product but for the use of the patented process.” *Id.*

The Senate report provided an analysis of how the first part of the test should be applied in the case of chemical intermediates. The report explained (S. Rep. No. 83 at 51):

If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

If there is more than one way to have arrived [at] Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.

As we noted above, the record makes clear that there is at least one commercially viable process for making cefaclor that does not involve the patented method of synthesizing enol cephems (including compound 6). Opos does not use that non-infringing process, but under the test set forth in the Senate report, it is enough to defeat the claim of infringement that there is another way of producing the intermediate, even if the alleged infringer does not use that alternative process.
The Senate Committee described the second portion of the two-part test for identifying a “material change” as follows (S. Rep. No. 83 at 50):

A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product [produced] by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be “material” if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually a change in the physical form of a product (e.g., the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a “material” change.

It seems fairly clear that under this second part of the test, the change from compound 6 to cefaclor would be regarded as a material change. The chemical properties of the two compounds are completely different, the “basic utility” of the products is different, and the chemical structure of the two products is significantly different. The changes between compound 6 and cefaclor go far beyond the minor changes that the report described as not material, such as the conversion to a salt, base, acid, hydrate or ester, or the removal of a protective group.

Lilly interprets the references in the Senate report to the “basic utility” and “properties” of the product of the patented process in a quite different manner. The “basic utility” and principal “property” of compound 6 in the U.S. market, according to Lilly, is to serve as an intermediate for the production of cefaclor. Because the defendants have “exploited” that utility or property, Lilly argues, compound 6 cannot be regarded as undergoing a “material change” in the course of its conversion to cefaclor.

Lilly’s argument distorts the terms “utility” and “properties” beyond recognition. The chemical and biological properties of compound 6 are plainly different from those of cefaclor, and the utility of the two compounds, as that term is conventionally used, is quite different. Cefaclor is a powerful oral antibiotic, with a set of chemical and biological properties that give it great utility in that regard; compound 6 has no such properties, and it has no significant utility as an antibiotic. Moreover, the premise of Lilly’s argument—that compound 6 has “utility” only as an intermediate in the preparation of cefaclor—is flawed. As the district court noted, compound 6 can be used to produce a variety of cephalosporin antibiotics, of which cefaclor is only one. While Lilly claims that cefaclor was the only derivative of compound 6 that was on the commercial market in the United States at the time of the district court’s decision in this case, other cephalosporin antibiotics that are producible from compound 6 were on sale in other countries, and proceedings were pending to obtain authorization to market at least one of those antibiotics in this country. Thus, despite Lilly’s creative effort to draw support from the references to “utility” and “properties” in the Senate report, the two-part test in the Senate report appears to offer no aid to Lilly’s statutory argument.
The conference report on the process patent bill contained only a short discussion of the “material change” issue, but that report reiterated the test found in both the House and Senate reports: that infringement can be found, even in the case of a significant change in the imported product, if “it would not have been possible or commercially viable to make the different [product] but for the patented process.” H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1087 (1988). See also Biotechnology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1562-63 (Fed. Cir. 1996) (citing the same test, in the biotechnology context, from the Senate report). Once again, because there is at least one known commercial method for making cefaclor that does not use the patented process, the language in the conference report on the Process Patent Amendments Act does not help Lilly.

At the end of this Long March through the legislative history, we cannot claim that the legislative background of the 1988 Act provides a conclusive answer to the question of how the “materially changed” clause should be construed in general, and how it should be applied to the facts of this case in particular. What we are able to say, however, is that the legislative history does not compel adoption of Lilly’s proposed analysis of the statute. In fact, to the extent that Congress intended the courts to look to the committee reports for guidance in construing the “materially changed” clause, the reports support the conclusion that the district court reached and that we uphold: that compound 6 is likely to be found to have been “materially changed” in the process of its conversion into cefaclor, and that the importation and sale of cefaclor is therefore not likely to be held to infringe Lilly’s rights under claim 5 of the ‘085 patent.

... Bayer AG v. Housey Pharmaceuticals, Inc.
340 F.3d 1367 (Fed. Cir. 2003)

Dyk, Judge:

Housey Pharmaceuticals, Inc. (“Housey”) appeals from the judgement ... dismissing its counterclaim for infringement of United States Patent Nos. 4,980,281, 5,266,464, 5,688,655, and 5,877,007 (collectively “the Housey patents”) for failure to state a claim. Because we conclude that infringement under 35 U.S.C. § 271(g) is limited to physical goods that were manufactured and does not include information generated by a patented process, and because the physical goods here (drug products) were not “manufactured” by a process claimed in the asserted patents, we affirm the dismissal of Housey’s infringement claims.

Background

Housey is the assignee of [the patents in suit], all entitled “Method of Screening for Protein Inhibitors and Activators.”¹ The patents are directed to “a method of

¹ All four Housey patents claim priority from U.S. Application No. 154,206 filed February 10, 1988, although the final three patents included additional disclosure via a continuation-in-part application filed August 10, 1989. For purposes of this appeal the patents are identical in all material aspects, and so will be described with respect to the final issued patent, U.S. Patent No. 5,877,007.
screening for substances which specifically inhibit or activate a particular protein affecting the cultural or morphological characteristics of the cell expressing the protein.” U.S. Pat. No. 5,877,007. The expression of the “particular protein” (referred to as the “protein of interest”) results in a change in one or more identifiable characteristics of the cells expressing it. According to the disclosed and claimed method, a cell line is produced that is characterized by a higher production of the protein of interest relative to an original cell line. By applying substances (“agents”) to both cell lines, it is possible to determine whether the agent is an activator or inhibitor of protein activity. Thus, for example, if a link between a protein and a disease is discovered, the disclosed method provides a process for identifying the effect that different agents have on the activity of the suspect protein.

On March 6, 2001, Bayer AG and Bayer Corporation (“Bayer”) filed a complaint seeking declaratory judgment of invalidity, unenforceability, and non-infringement of the Housey patents. On March 27, 2001, Housey filed an answer to the complaint and asserted a counterclaim for infringement of the Housey patents. The counterclaim alleged that Bayer “directly infringed claims of each of the patents-in-suit” and “contributed to infringement or induced others to infringe the patents-in-suit.” Additionally, Housey alleged that Bayer “infringed the method claims of the patents in suit pursuant to 35 U.S.C. § 271(g).” The factual basis of Housey’s infringement claim as stated in the counterclaim was that:

Pursuant to 35 U.S.C. § 295, this Court may presume that a product was made [by Housey’s] patented methods where there is a substantial likelihood that it was so made by and [Housey] has made reasonable efforts to determine the process actually used. Here, there is substantial likelihood that [Housey’s] methods were used by Bayer to make the characterization of a pharmacologically active agent. Further, [Housey] has requested the defendants to identify the methods used in its facilities, but the [sic] Bayer has failed to do so. [Housey] has made the required reasonable efforts.

On April 16, 2001, Bayer filed a motion to dismiss … with respect to Housey’s counterclaim for infringement under § 271(g), arguing that the provision “applies only to methods of manufacture, and does not apply to [Housey’s] method patent claims *** [which] cover methods of use, not methods of manufacturing.” Bayer argued that “Section 271(g) is inapplicable as a matter of law and [Housey’s] claim for infringement of its method claims under § 271(g) should be dismissed.” Bayer characterized Housey’s infringement allegations as follows:

1. Bayer is liable as an infringer when it sells in the United States a pharmaceutical composition containing a substance determined to be an inhibitor or activator of a target protein by use either in the United States or abroad of the [Housey] United States patented methods.

2. Bayer AB is liable as an infringer when it imports into the United States research data or information obtained from using the [Housey] patented methods.

In its opposition to Bayer’s motion to dismiss, Housey similarly described its counterclaim for infringement under § 271(g) as comprising two separate claims, the first of which was directed to “the critical information, the identification and
characterization of a drug, [which] is made by [the] patented process” and the second of which was directed to “the drug made by [the] patented process.” The parties, therefore, were in substantial agreement as to the scope of the counterclaim for infringement, characterizing it as extending to both the importation of a pharmaceutical composition identified by the patented process and the importation of information generated by the patented process.

... Discussion ...

I

This case presents questions concerning the interpretation of § 271(g) ... . We are concerned here in particular with the meaning of the phrase “a product which is made by a [patented] process.” We have construed portions of this statute in a number of previous cases. However, this case presents issues not previously addressed. ...

II

Housey offers two theories as to why § 271(g) is applicable here. First, it contends that the information produced by Bayer using the patented processes claimed in the Housey patents is itself a product made by a patented process. Bayer, in turn, argues that (1) the word “made” means “manufactured” and that (2) information is not a manufactured product. There is no serious dispute between the parties concerning the second of these two propositions: if only products that have been “manufactured” are within the scope of 35 U.S.C. § 271(g), it necessarily follows that the statute applies only to physical goods and that information is not included. Webster’s Third New International Dictionary defines the verb form of “manufacture” as “to make (as raw material) into a product suitable for use *** to make from raw materials by hand or by machinery.” Webster’s at 1378 (1968). Similarly, Random House Webster’s Unabridged Dictionary defines “manufacture” as “the making of goods or wares by manual labor or by machinery.” Random House at 1172 (2d ed. 1998) (emphasis added). These definitions are consistent in referring to tangible objects and not intangibles such as information. Thus, the production of information is not within the scope of processes of “manufacture.” Housey, in fact, does not argue that information is within the statute if the term “made” is construed to mean “manufactured.” We thus turn to the central question—whether the statutory term “made” means “manufactured.”

III

4 In American Fruit Growers, Inc. v. Brogdex Co., the Supreme Court defined the verb form of “manufacture” as “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.” 283 U.S. 1, 11 (1931) (quoting the Century Dictionary). An “article” is “one of a class of material things *** piece of goods: COMMODITY.” Webster’s at 123 (emphasis added).
As used in the statute, the term “made” is the past tense of the verb “make.” The dictionaries offer multiple definitions of the term “make.” Some definitions are limited to manufacturing, for example, “to bring (a material thing) into being by forming, shaping, or altering material: FASHION, MANUFACTURE.” Webster’s at 1363. Other definitions broadly encompass activities in addition to manufacturing. For example, Webster’s defines “make” as “form as a result of calculation or design.” Id. Under these circumstances the text is ambiguous, and we must look beyond the particular language being construed.


There are other indications as well that the statute is concerned exclusively with products that are physical goods produced by a manufacturing process. One statutory exception to section 271(g) rules out infringement where the allegedly infringing product “is materially changed by subsequent processes.” 35 U.S.C. § 271(g)(1). Housey’s position that information itself is a “product” is difficult to reconcile with the existence of this exception, which appears to contemplate a change in a physical product. Similarly, the second exception to section 271(g), which provides that there is no infringement where the accused product “becomes a trivial and nonessential component of another product,” also appears to contemplate a physical product.

... 

Finally, reading the statute to cover processes other than manufacturing processes could lead to anomalous results. The importation of information in the abstract (here, the knowledge that a substance possesses a particular quality) cannot be easily controlled. As Bayer points out, a person possessing the allegedly infringing information could, under Housey’s interpretation, possibly infringe by merely entering the country. Such an illogical result cannot have been intended. See Paul v. Davis, 424 U.S. 693, 698-99 (1976).

Under these circumstances we think it is best to leave to Congress the task of expanding the statute if we are wrong in our interpretation. Congress is in a far bet-

5 Random House states: “to bring into existence by shaping or changing material, combining parts, etc.” Random House at 1161.
6 Random House states: “to bring into existence by shaping or changing material, combining parts, etc.” Random House at 1161.
ter position to draw the lines that must be drawn if the product of intellectual processes rather than manufacturing processes are to be included within the statute.

We, therefore, hold that in order for a product to have been “made by a process patented in the United States” it must have been a physical article that was “manufactured” and that the production of information is not covered.

VI

This, however, is not the end of the inquiry. As characterized by Bayer in its motion to dismiss, Housey’s counterclaim of infringement also extended to “a pharmaceutical composition containing a substance determined to be an inhibitor or activator of a target protein by use either in the United States or abroad of the [Housey] United States patented methods.” In opposing dismissal, Housey agreed that the counterclaim included drug products, stating that “the drug [itself was] made by [the] patented process.” The factual basis upon which Housey made its counterclaim for infringement by the drug product was that:

Pursuant to 35 U.S.C. § 295, [the district court] may presume that a product was made [by Housey’s] patented methods where there is a substantial likelihood that it was so made by and [Housey] has made reasonable efforts to determine the process actually used. Here, there is substantial likelihood that [Housey’s] methods were used by Bayer to make the characterization of a pharmacologically active agent.

Thus, Housey alleged that, as a result of the claimed research process, Bayer produced drugs using information created by the patented processes.

It is beyond dispute that a drug is a physical product that has been manufactured. The issue, therefore, is the necessary relationship under the statute between the “process patented in the United States” and the resulting product, i.e., we must determine whether a drug that was identified as useful through the use of a patented process is a “product which [was] made by [that] process.” 35 U.S.C. § 271(g). As we have previously noted:

[t]he statute does not specify what products will be considered to have been ‘made by’ the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity to the product of the patented process on a case-by-case basis.

Bio-Technology General Corp. v. Genetech, Inc., 80 F.3d 1553, 1561 (Fed. Cir. 1996). In Bio-Technology we affirmed the district court’s ruling that a protein made by a host organism expressing an inserted plasmid was a product “made by” the patented process for creating the plasmid itself. Id. Here, unlike the process in Bio-Technology, the patented process is not used in the actual synthesis of the drug product. We agree with the district court’s conclusion that “processes of identification and generation of data are not steps in the manufacture of a final drug product.”

The statute requires that the allegedly infringing product have been “made by a process patented in the United States.” 35 U.S.C. § 271(g). The pertinent dictionary definitions of “by” are “through the means or instrumentality of[;] *** through the direct agency of[;] *** through the medium of[;] *** through the
work or operation of.” *Webster’s* at 307. Thus, the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured. A drug product, the characteristics of which were studied using the claimed research processes, therefore, is not a product “made by” those claimed processes. …

...  

**A Note about the NTP Case**

Earlier in this chapter, you considered NTP *v. Research In Motion*, the BlackBerry case. In a portion of the opinion not excerpted earlier, the Federal Circuit considered an infringement theory that was based on § 271(g), thus prompting discussion of the *Housey* case. That portion of *NTP* is as follows:

... The next question is whether RIM can be said to “import[] into *** or offer[] to sell, sell[], or use[] within the United States a product which is made by a process patented in the United States” and thus infringe under 35 U.S.C. § 271(g). The district court held that “wireless electronic mail” specially formatted by a patented process can be a “product” under section 271(g). The district court compared the breadth of “product” to the breadth of patentable subject matter, cited to *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) [(holding that a genetically modified bacterium is a patentable “manufacture” under 35 U.S.C. § 101)], and explained that specially formatted wireless e-mail is not naturally occurring, an abstract idea, or a physical phenomenon.

RIM argues that the product created by the NTP process is data or information, and that *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003), held that section 271(g) does not cover the production of intangible items. NTP counters that *Bayer* held only that a “product” cannot be “information in the abstract.” NTP asserts that the “email packets” flowing from the BES, to the interface, and back to the RF receiver, have a “tangible” structure which includes the interface address, an RF address, and the inputted message. ... NTP adds that RIM “manufactures” email into its tangible structure and “imports” email using patented methods, in part, by replacing the interface address with the RF receiver address at the interface Relay. RIM responds that the email packets that it may transfer into the United States are not manufactured, physical goods, and therefore are not “products” under § 271(g).

In *Bayer*, we considered whether research data from the performance of a method to identify substances, which inhibit or activate a protein affecting characteristics of the cell, was “a product which is made by a process.” 340 F.3d at 1370. We held that “the production of information is not covered” by § 271(g), explaining that the process must be for the “manufacturing” of “a physical article.” *Id.* at 1377. In this case, the relevant claims are directed to

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12 *Random House* similarly defines “by” as “through the agency, efficacy, work, participation, or authority of.” *Random House* at 287.
methods for the transmission of information in the form of email messages. Because the “transmission of information,” like the “production of information,” does not entail the manufacturing of a physical product, § 271(g) does not apply to the asserted method claims in this case any more than it did in Bayer.

**Defenses: Exhaustion, Reconstruction & Repair**

**Bowman v. Monsanto**

133 S. Ct. 1761 (2013)

Kagan, Justice:

…

Respondent Monsanto invented a genetic modification that enables soybean plants to survive exposure to glyphosate, the active ingredient in many herbicides (including Monsanto’s own Roundup). Monsanto markets soybean seed containing this altered genetic material as Roundup Ready seed. Farmers planting that seed can use a glyphosate-based herbicide to kill weeds without damaging their crops. Two patents issued to Monsanto cover various aspects of its Roundup Ready technology, including a seed incorporating the genetic alteration.

Monsanto sells, and allows other companies to sell, Roundup Ready soybean seeds to growers who assent to a special licensing agreement. That agreement permits a grower to plant the purchased seeds in one (and only one) season. He can then consume the resulting crop or sell it as a commodity, usually to a grain elevator or agricultural processor. But under the agreement, the farmer may not save any of the harvested soybeans for replanting, nor may he supply them to anyone else for that purpose. These restrictions reflect the ease of producing new generations of Roundup Ready seed. Because glyphosate resistance comes from the seed’s genetic material, that trait is passed on from the planted seed to the harvested soybeans: Indeed, a single Roundup Ready seed can grow a plant containing dozens of genetically identical beans, each of which, if replanted, can grow another such plant—and so on and so on. The agreement’s terms prevent the farmer from co-opting that process to produce his own Roundup Ready seeds, forcing him instead to buy from Monsanto each season.

Petitioner Vernon Bowman is a farmer in Indiana who, it is fair to say, appreciates Roundup Ready soybean seed. He purchased Roundup Ready each year, from a company affiliated with Monsanto, for his first crop of the season. In accord with the agreement just described, he used all of that seed for planting, and sold his entire crop to a grain elevator (which typically would resell it to an agricultural processor for human or animal consumption).

Bowman, however, devised a less orthodox approach for his second crop of each season. Because he thought such late-season planting “risky,” he did not want to pay the premium price that Monsanto charges for Roundup Ready seed. He therefore went to a grain elevator; purchased “commodity soybeans” intended for
human or animal consumption; and planted them in his fields.¹ Those soybeans came from prior harvests of other local farmers. And because most of those farmers also used Roundup Ready seed, Bowman could anticipate that many of the purchased soybeans would contain Monsanto’s patented technology. When he applied a glyphosate-based herbicide to his fields, he confirmed that this was so; a significant proportion of the new plants survived the treatment, and produced in their turn a new crop of soybeans with the Roundup Ready trait. Bowman saved seed from that crop to use in his late-season planting the next year—and then the next, and the next, until he had harvested eight crops in that way. Each year, that is, he planted saved seed from the year before (sometimes adding more soybeans bought from the grain elevator), sprayed his fields with glyphosate to kill weeds (and any non-resistant plants), and produced a new crop of glyphosate-resistant—i.e., Roundup Ready—soybeans.

After discovering this practice, Monsanto sued Bowman for infringing its patents on Roundup Ready seed. Bowman raised patent exhaustion as a defense, arguing that Monsanto could not control his use of the soybeans because they were the subject of a prior authorized sale (from local farmers to the grain elevator). The District Court rejected that argument, and awarded damages to Monsanto of $84,456. The Federal Circuit affirmed. … We granted certiorari to consider the important question of patent law raised in this case and now affirm.

II

The doctrine of patent exhaustion limits a patentee’s right to control what others can do with an article embodying or containing an invention. Under the doctrine, “the initial authorized sale of a patented item terminates all patent rights to that item.” Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617, 625 (2008). And by “exhaust[ing] the [patentee’s] monopoly” in that item, the sale confers on the purchaser, or any subsequent owner, “the right to use [or] sell” the thing as he sees fit. United States v. Univis Lens Co., 316 U.S. 241, 249-250 (1942). We have explained the basis for the doctrine as follows: “[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward *** by the sale of the article”; once that “purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold.” Id. at 251.

Consistent with that rationale, the doctrine restricts a patentee’s rights only as to the “particular article” sold; it leaves untouched the patentee’s ability to prevent a buyer from making new copies of the patented item. “[T]he purchaser of the [patented] machine *** does not acquire any right to construct another machine either for his own use or to be vended to another.” Mitchell v. Hawley, 83 U.S. (16

¹ Grain elevators … purchase grain from farmers and sell it for consumption; under federal and state law, they generally cannot package or market their grain for use as agricultural seed. See 7 U.S.C. § 1571; Ind. Code § 15-15-1-32. But because soybeans are themselves seeds, nothing (except, as we shall see, the law) prevented Bowman from planting, rather than consuming, the product he bought from the grain elevator.
Wall.) 544, 548 (1873); see Wilbur-Ellis Co. v. Kuther, 377 U.S. 422, 424 (1964) (holding that a purchaser’s “reconstruction” of a patented machine “would impinge on the patentee’s right ‘to exclude others from making’ ** the article” (quoting 35 U.S.C. § 154)). Rather, “a second creation” of the patented item “call[s] the monopoly, conferred by the patent grant, into play for a second time.” Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 346 (1961). That is because the patent holder has “received his reward” only for the actual article sold, and not for subsequent recreations of it. Univis, 316 U.S. at 251. If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale. Bowman himself disputes none of this analysis as a general matter: He forthrightly acknowledges the “well settled” principle “that the exhaustion doctrine does not extend to the right to ‘make’ a new product.” Brief for Petitioner 37 (citing Aro, 365 U.S. at 346).

Unfortunately for Bowman, that principle decides this case against him. Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator; so too he could consume the beans himself or feed them to his animals. Monsanto, although the patent holder, would have no business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto’s permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best; applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how “to ‘make’ a new product,” to use Bowman’s words, when the original product is a seed. See Webster's Third New International Dictionary 1363 (1961) (“make” means “cause to exist, occur, or appear,” or more specifically, “plant and raise (a crop)” ). Because Bowman thus reproduced Monsanto’s patented invention, the exhaustion doctrine does not protect him.

Were the matter otherwise, Monsanto’s patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, “receiv[e] [its] reward” for the first seeds it sells. Univis, 316 U.S. at 251. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed

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3 This conclusion applies however Bowman acquired Roundup Ready seed: The doctrine of patent exhaustion no more protected Bowman’s reproduction of the seed he purchased for his first crop (from a Monsanto-affiliated seed company) than the beans he bought for his second (from a grain elevator). The difference between the two purchases was that the first—but not the second—came with a license from Monsanto to plant the seed and then harvest and market one crop of beans. We do not here confront a case in which Monsanto (or an affiliated seed company) sold Roundup Ready to a farmer without an express license agreement. For reasons we explain below, we think that case unlikely to arise. And in the event it did, the farmer might reasonably claim that the sale came with an implied license to plant and harvest one soybean crop.
once, whether from Monsanto, a competitor, or (as here) a grain elevator. The
grower could multiply his initial purchase, and then multiply that new creation, ad
infinitum—each time profiting from the patented seed without compensating its
inventor. Bowman’s late-season plantings offer a prime illustration. After buying
beans for a single harvest, Bowman saved enough seed each year to reduce or elimi-
nate the need for additional purchases. Monsanto still held its patent, but received
no gain from Bowman’s annual production and sale of Roundup Ready soybeans.
The exhaustion doctrine is limited to the “particular item” sold to avoid just such a
mismatch between invention and reward.

Our holding today also follows from J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred
Intr’t, Inc., 534 U.S. 124 (2001). We considered there whether an inventor could
get a patent on a seed or plant, or only a certificate issued under the Plant Variety
Protection Act (PVPA), 7 U.S.C. § 2321 et seq. We decided a patent was available,
rejecting the claim that the PVPA implicitly repealed the Patent Act’s coverage of
seeds and plants. On our view, the two statutes established different, but not con-
flicting schemes: The requirements for getting a patent “are more stringent than
those for obtaining a PVP certificate, and the protections afforded” by a patent are
correspondingly greater. J.E.M., 534 U.S. at 142. Most notable here, we explained
that only a patent holder (not a certificate holder) could prohibit “[a] farmer who
legally purchases and plants” a protected seed from saving harvested seed “for re-
planting.” Id. at 140; see id. at 143 (noting that the Patent Act, unlike the PVPA,
contains “no exemption” for “saving seed”). That statement is inconsistent with
applying exhaustion to protect conduct like Bowman’s. If a sale cut off the right to
control a patented seed’s progeny, then (contrary to J.E.M.) the patentee could not
prevent the buyer from saving harvested seed. Indeed, the patentee could not stop
the buyer from selling such seed, which even a PVP certificate owner (who, recall,
is supposed to have fewer rights) can usually accomplish. See 7 U.S.C. §§ 2541, 2543.
Those limitations would turn upside-down the statutory scheme J.E.M. described.

Bowman principally argues that exhaustion should apply here because seeds are
meant to be planted. The exhaustion doctrine, he reminds us, typically prevents a
patentee from controlling the use of a patented product following an authorized
sale. And in planting Roundup Ready seeds, Bowman continues, he is merely using
them in the normal way farmers do. Bowman thus concludes that allowing Monsan-
to to interfere with that use would “create an impermissible exception to the
exhaustion doctrine” for patented seeds and other “self-replicating technologies.”
Brief for Petitioner 16.

But it is really Bowman who is asking for an unprecedented exception—to what
he concedes is the “well settled” rule that “the exhaustion doctrine does not extend
to the right to ‘make’ a new product.” Reproducing a patented article no doubt
“uses” it after a fashion. But as already explained, we have always drawn the boun-
daries of the exhaustion doctrine to exclude that activity, so that the patentee retains
an undiminished right to prohibit others from making the thing his patent protects.
See, e.g., Cotton-Tie Co. v. Simmons, 106 U.S. 89, 93-94 (1882) (holding that a pur-
chaser could not “use” the buckle from a patented cotton-bale tie to “make” a new
tie). That is because, once again, if simple copying were a protected use, a patent
would plummet in value after the first sale of the first item containing the invention. The undiluted patent monopoly, it might be said, would extend not for 20 years (as the Patent Act promises), but for only one transaction. And that would result in less incentive for innovation than Congress wanted. Hence our repeated insistence that exhaustion applies only to the particular item sold, and not to reproductions.

Nor do we think that rule will prevent farmers from making appropriate use of the Roundup Ready seed they buy. Bowman himself stands in a peculiarly poor position to assert such a claim. As noted earlier, the commodity soybeans he purchased were intended not for planting, but for consumption. Indeed, Bowman conceded in deposition testimony that he knew of no other farmer who employed beans bought from a grain elevator to grow a new crop. So a non-replicating use of the commodity beans at issue here was not just available, but standard fare. And in the more ordinary case, when a farmer purchases Roundup Ready seed *qua* seed—that is, seed intended to grow a crop—he will be able to plant it. Monsanto, to be sure, conditions the farmer’s ability to reproduce Roundup Ready; but it does not—could not realistically—preclude all planting. No sane farmer, after all, would buy the product without some ability to grow soybeans from it. And so Monsanto, predictably enough, sells Roundup Ready seed to farmers with a license to use it to make a crop. Applying our usual rule in this context therefore will allow farmers to benefit from Roundup Ready, even as it rewards Monsanto for its innovation.

Still, Bowman has another seeds-are-special argument: that soybeans naturally “self-replicate or ‘sprout’ unless stored in a controlled manner,” and thus “it was the planted soybean, not Bowman” himself, that made replicas of Monsanto’s patented invention. But we think that blame-the-bean defense tough to credit. Bowman was not a passive observer of his soybeans’ multiplication; or put another way, the seeds he purchased (miraculous though they might be in other respects) did not spontaneously create eight successive soybean crops. As we have explained, Bowman devised and executed a novel way to harvest crops from Roundup Ready seeds without paying the usual premium. He purchased beans from a grain elevator anticipating that many would be Roundup Ready; applied a glyphosate-based herbicide in a way that culled any plants without the patented trait; and saved beans from the rest for the next season. He then planted those Roundup Ready beans at a chosen time; tended and treated them, including by exploiting their patented glyphosate-resistance; and harvested many more seeds, which he either marketed or saved to begin the next cycle. In all this, the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto’s patented invention.

Our holding today is limited—addressing the situation before us, rather than every one involving a self-replicating product. We recognize that such inventions are becoming ever more prevalent, complex, and diverse. In another case, the article’s self-replication might occur outside the purchaser’s control. Or it might be a necessary but incidental step in using the item for another purpose. Cf. 17 U.S.C. § 117(a)(1) (“[I]t is not [a copyright] infringement for the owner of a copy of a computer program to make *** another copy or adaptation of that computer program provide[d] that such a new copy or adaptation is created as an essential step in
the utilization of the computer program”). We need not address here whether or how the doctrine of patent exhaustion would apply in such circumstances. In the case at hand, Bowman planted Monsanto’s patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct. We accordingly affirm the judgment of the Court of Appeals for the Federal Circuit.

**Fuji Photo Film Co. v. International Trade Comm’n**

474 F.3d 1281 (Fed. Cir. 2007)

Dyk, Judge:

Appellants Fuji Photo Film Co., Ltd. (“Fuji”) and Jack Benun (“Benun”), one of the principals of Jazz Photo Corp. (“Jazz”), separately appeal the International Trade Commission’s (“Commission”) final determination concerning civil penalties for violation of a cease and desist order issued to Jazz and “its principals, stockholders, officers, directors, employees, [and] agents.” The cease and desist order barred Jazz from importing (or selling, marketing, advertising, distributing, etc. previously imported) disposable cameras that infringed fifteen of Fuji’s patents. The central questions before the Commission were whether: (1) the cameras were first sold abroad (making their refurbishment infringing regardless of whether they were repaired or reconstructed); and (2) whether the processes Jazz used to refurbish the cameras first sold in the United States constituted permissible repair or impermissible reconstruction. Fuji challenges the order on the ground that the Commission erred in finding that certain of Jazz’s lens-fitted film packages (“LFFPs” or “cameras”) were permissibly repaired. On appeal Benun, the principal consultant and later Chief Operating Officer (“COO”) of Jazz, challenges the order insofar as it imposes civil penalties.

We conclude that Fuji lacked standing to bring this appeal. With respect to Benun’s appeal, we conclude that the Commission had the authority to issue an order against Benun; that the order applied to Benun; and that adequate notice was provided that the order applied to Benun. We also hold that substantial evidence supports the finding that the majority of the cameras were first sold abroad and that, while the Commission did not err in finding impermissible reconstruction with respect to most of the cameras first sold in the United States, the Commission erred in ruling that the replacement of the full backs constituted impermissible reconstruction.

... 

Background

Cases arising from the same factual background have been before this court four other times [including in … Jazz Photo Corp. v. Int’l Trade Comm’n, 264 F.3d 1094 (Fed. Cir. 2001) (“Jazz I”). We will therefore recite only the facts most relevant to the present appeal.

I
Miller's Patent Cases

Fuji is the owner of fifteen patents directed at LFFPs, popularly known as disposable, single use, or one time use cameras. Fuji and its licensees, Eastman Kodak Co. and Konica Corp., manufacture and sell LFFPs. The LFFP consists of a plastic shell that is encased in a cardboard cover and equipped with a button-activated shutter, a lens, a viewfinder, a film advance mechanism, and optional flash units and buttons. The LFFP is preloaded with both film and a film cartridge into which the exposed film winds. The typical consumer of these inexpensive cameras brings the entire LFFP to a film processor to be developed and receives back only the negatives and prints, but not the LFFP itself. During the period in question Jazz collected used LFFP shells originally made by Fuji or its licensees, inserted new film and otherwise refurbished the shells, and sold them in the United States. Some of the shells that Jazz collected were originally sold by Fuji and its licensees in the United States, while others were first sold abroad.

II

On March 25, 1998, the Commission instituted an investigation against 27 respondents that imported and sold LFFPs, including Jazz, to determine whether they were violating one or more claims of Fuji’s fifteen patents. The Commission found that Jazz and other respondents were infringing the patents unless the respondents’ activities involved permissible repair. Thus, a central issue was whether cameras first sold in the United States were permissibly repaired or impermissibly reconstructed. The Commission held that the respondents had the burden of proof on this issue. To some extent, the Commission found that the respondents had failed to satisfy their burden because they had not supplied complete information about their refurbishment processes, which occurred abroad. However, the Commission also identified eight common steps that Jazz and some additional respondents admitted utilizing. The Commission concluded that these eight common steps constituted impermissible reconstruction.¹

Discussion

... Benun argues ... that Jazz did not violate the cease and desist order because Jazz’s activities constituted permissible repair. Repair is an affirmative defense to a claim of infringement, and Benun, as the party raising the affirmative defense, had the burden of establishing this defense by a preponderance of the evidence. ... “The Supreme Court has taken an expansive view of conduct that constitutes permissible repair of a patented combination of unpatented elements.” Sage Prods., Inc. v. Devon Indus., Inc., 45 F.3d 1575, 1578 (Fed. Cir. 1995).

¹ The eight steps were: 1) removing the cardboard cover; 2) opening the LFFP body; 3) replacing the winding wheel or modifying the film cartridge to be inserted; 4) resetting the film counter; 5) replacing the battery in flash LFFPs; 6) winding new film out of a canister onto a spool or into a roll; 7) resealing the LFFP body using tape and/or glue; 8) applying a new cardboard cover.
The affirmative defense of repair only applies to products whose patent rights have been exhausted through a first sale in the United States. *Jazz I*, 264 F.3d at 1105. The Commission concluded that 40% of the LFFPs in issue were first sold abroad and had unexhausted patent rights. This conclusion was supported by substantial evidence. It was based on studies conducted by Fuji’s expert that used the identifying numbers printed on the LFFPs and Fuji’s production and shipping databases to determine where samples of Fuji-type LFFPs with Jazz packaging (*i.e.*, ones that were refurnished by Jazz) were first sold.

... 

Benun ... contends that the Commission erred in concluding that no evidence had been provided of the process used for refurbishing most of the cameras in issue. The Commission found that “there is a lack of complete and credible information verifying the LFFP refurbishing process at many of Jazz’s supplier factories” and therefore that Jazz had failed to prove permissible repair for cameras made at these factories. The burden was on Benun, as the party seeking to invoke the affirmative defense of repair, to provide “evidence to show that the activities performed in processing the used cameras constituted permissible repair.” *Jazz I*, 264 F.3d at 1102.

Benun argues that the Commission erred in finding the evidence insufficient to show the processes used at many facilities. First, Benun contends that the Commission erroneously held that videotape evidence was essential. We do not read the Commission decision as imposing any such absolute requirement with respect to videotape evidence; it merely held that Benun’s videotape evidence in many instances was not authenticated and credited expert testimony that the videotapes were not reliable evidence of what transpired at these factories. Second, Benun asserts that Jazz required its suppliers to use only Jazz-approved processes, but fails to show that he provided any evidence as to what these processes actually involved. Third, Benun relies on Fuji’s failure to visit factories until 2003 or identify any patented parts that were replaced, but ignores the fact that Jazz, not Fuji, had the burden of proof. Finally, Benun points to testimony by several witnesses about how the cameras were refurbished. This testimony was only from employees of Jazz and its suppliers, not disinterested witnesses, and the Commission could properly decline to credit it.

13 A different rule applies in the copyright context. In *Quality King Distributors, Inc. v. L’anza Research International, Inc.*, 523 U.S. 135 (1998), the Supreme Court held that “the owner of goods lawfully made under the [Copyright] Act is entitled to the protection of the first sale doctrine in an action in a United States court even if the first sale occurred abroad.” *Id.* at 145 n.14.

[ Ed. Note—The Supreme Court recently reaffirmed a broad exhaustion defense to copyright. See *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013). ]
Finally, as to some of the cameras, the Commission found that the replacement of the full backs of the cameras involved impermissible reconstruction. Benun contends that these cameras were permissibly repaired. “The application of the law of repair and reconstruction to fact is *** a legal determination, and is reviewed without deference.” *Jazz I*, 264 F.3d at 1099.

First, contrary to Fuji’s assertion, our original decision in *Jazz I* did not limit the scope of permissible repair to the eight common steps it considered; rather we did not reach the question of what other activities constituted permissible repair. *See Jazz I*, 264 F.3d at 1109 (“We can not exculpate unknown processes from the charge of infringing reconstruction.”). On appeal in this case, the Commission and Benun agree that the eight step refurbishment discussed in *Jazz I* and the nineteen step refurbishment described in the Commission order here both involve permissible repair. The question then is whether one additional action by Jazz, the addition of a new plastic back cover, converts the activity into impermissible reconstruction.\(^{15}\)

In *Husky Injection Molding Systems Ltd. v. R & D Tool & Engineering Co.*, 291 F.3d 780 (Fed. Cir. 2002), we concluded that the replacement of a spent part was a fundamental example of a permissible repair. *Id.* at 785-86. Benun contends that the back covers were spent parts and their replacement was permissible repair. This is so, he argues, because as a practical matter the backs had to be broken to remove the film, and once new film was inserted the back covers could no longer serve their function of enclosing the camera and keeping light out. The backs therefore were spent and could properly be replaced. Although Fuji did not intend the LFFP to be refurbished, “the patentee’s unilateral intent, without more, does not bar reuse of the patented article, or convert repair into reconstruction.” *Jazz I*, 264 F.3d at 1106; *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1453 (Fed. Cir. 1997).

Benun’s factual premise that the backs had to be broken to repair the film is not contested by the Commission on appeal. This court and other tribunals have repeatedly concluded that, in view of the continued utility of the shutter mechanism, lens, viewfinder, film advance mechanism, and other significant parts in the original camera, replacing the film is a permissible repair and reattaching or replacing a part that must be removed or broken to replace the film also constitutes permissible repair. *See Jazz I*, 264 F.3d at 1106 (reattachment of the back cover); *Fuji II*, 249 F. Supp. 2d. 434, 446 (D.N.J. 2003), *aff’d*, 394 F.3d 1368 (Fed. Cir. 2005) (removal of the film door that was broken in removing the film). Significantly, there is no contention here that the extent of the refurbishment is disproportionate to the overall value of the parts that were not replaced. *See Husky*, 291 F.3d at 786-87; *Jazz I*, 264 F.3d at 1106.

\(^{15}\) This issue arises in the context of an extensive market for refurbishment of the cameras in question. *See Sandvik Aktiebolag v. E.J. Co.*, 121 F.3d 669, 673 (Fed. Cir. 1997) (holding that the existence of a market to manufacture or service spent parts tends to prove that there is a reasonable expectation that the spent parts can be permissibly replaced).
In a variety of other contexts we have also held that replacement of a part that must be broken or removed to repair the device does not convert permissible repair into impermissible reconstruction. For example, in *Bottom Line Management, Inc. v. Pan Man, Inc.*, 228 F.3d 1352 (Fed. Cir. 2000), we found that “incidental repairs to minor damages” necessary to replace a spent part did not justify a finding of reconstruction. *Id.* at 1356. In that case studs that held a spent part in place had to be broken in order to remove that part for replacement, and we concluded that replacement of these studs did not justify a finding of reconstruction. *Id.* at 1356. Similarly, in *Everpure, Inc. v. Cuno, Inc.*, 875 F.2d 300, 303 (Fed. Cir. 1989), we held that a patentee who designed a product so that the neck which connects a filtering cartridge to the base of the device had to be replaced in order to replace the worn-out cartridge itself could not claim impermissible reconstruction from the replacement of the neck. We concluded that “Everpure and Everpure alone made the business decision to sell disposable cartridges and to render its filter irreplaceable without replacement of the entire cartridge.” *Id.* Likewise, in this case, it would appear that Jazz’s actions in replacing the back covers, which must be broken in order to replace the spent film and film cartridge, does not justify a finding of impermissible reconstruction.

The Commission’s sole basis for reaching a contrary conclusion was its reliance on an erroneous repair-reconstruction test. The Commission found that by replacing the back cover, Jazz was completely replacing two horizontal ribs that satisfied the “means for exerting force” element of claim 5 of the ’495 patent, as well as completely replacing two other elements of claim 5 (the film and the film cartridge) and partially replacing the fourth element (the light-tight film case). The Commission said, “if a component is integral to a specific patent claim, and it is replaced with a new part, such replacement would weigh heavily towards a finding of reconstruction.” Here the back cover of the LFFPs was part of a patent directed to a combination of elements; the back cover was not separately patented.

The Supreme Court in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961), rejected a test for repair/reconstruction that would look to whether an “essential” or “distinguishing” part of the patented combination had been replaced. *Id.* at 345. In doing so, the Court concluded “that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant” and “that there is no legally recognizable or protected ‘essential’ element, ‘gist’ or ‘heart’ of the invention in a combination

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16 Claim 5 of the ’495 patent states in full:

5. A lens-fitted photographic film package having exposure effecting means and a taking lens comprising: a light-tight film case which must be destroyed to open the same; a film which is formed in a roll and contained in a film roll chamber of said light-tight film case; a film container received in said light-tight film case into which said film, after exposure, is advanced frame by frame and wound in a roll; and means to exert a frictional force on said film upon said film being advanced.
patent.” *Id.* at 344-45. We see no material difference between the Commission’s test that focused on whether an “integral” component has been replaced, and the tests previously rejected by the Supreme Court that focus on whether an “essential” or “distinguishing” part, or part that is at the “gist” or “heart” of the invention, has been replaced. *See Husky*, 291 F.3d at 787 (noting that the Supreme Court has “eschewed the suggestion that the legal distinction between ‘reconstruction’ and ‘repair’ should be affected by whether the element of the combination that has been replaced is an ‘essential’ or ‘distinguishing’ part of the invention”) (quoting *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 217 (1980)). Moreover, the Commission’s test is not in accord with our earlier decision in *Jazz I* itself: Two of the eight steps found by this court to be permissible repair in that decision likewise replaced elements of claim 5 of the ’495 patent—the film and the film cartridge. 264 F.3d at 1098.

Thus, we conclude that the Commission erred in holding that the cameras in which full backs were replaced were impermissibly reconstructed; we hold that the replacement of the full backs was part of a permissible repair. We accordingly remand to the Commission for the limited purpose of considering an appropriate adjustment in the amount of civil penalties in light of our holding that the 998,250 LFFPs refurbished by replacing the full backs were permissibly repaired.

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**Editor’s Note**

On April 14, 2015, the Federal Circuit ordering that an appeal styled *Lexmark Int’l, Inc. v. Impression Prods., Inc.*, Nos. 2014-1617, -1619, be heard en banc. (The case had been briefed and, on March 6, 2015, argued, but “[t]he panel [that heard argument] sua sponte requested a poll on whether to consider th[e] case en banc in the first instance,” Order at 2, and a majority vote took it en banc.)

The court ordered new briefing on the following issues:

(a) The case involves certain sales, made abroad, of articles patented in the United States. In light of *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2012), should this court overrule *Jazz Photo Corp. v. International Trade Comm’n*, 264 F.3d 1094 (Fed. Cir. 2001), to the extent it ruled that a sale of a patented item outside the United States never gives rise to United States patent exhaustion.

(b) The case involves (i) sales of patented articles to end users under a restriction that they use the articles once and then return them and (ii) sales of the same patented articles to resellers under a restriction that resales take place under the single-use-and-return restriction. Do any of those sales give rise to patent exhaustion? In light of *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), should this court overrule *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), to the extent it ruled that a sale of a patented article, when the sale is made under a restriction that is otherwise lawful and within the scope of the patent grant, does not give rise to patent exhaustion?

Order at 2. The case remains pending as of the time of this writing.
Chapter 8: Patentable Subject Matter

Biotech & Medicine

What is patentable? What is not? The operative statutory provision has, with the exception of one word, been the same since 1793:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.


What common thread runs through these statutory categories of patentable subject matter? Human intervention appears to be key to at least three of the four groups: “machines” and “manufactures” are not found in nature, and naturally occurring materials are not “composed.” And the patentable subject matter requirement has, in fact, been easy to apply for most technologies.

Two technologies—genome modifications, and computer-implemented processes—have presented challenging line-drawing problems. In two cases, decided a year apart over 30 years ago, the Supreme Court considered the patent-eligibility of inventions from each of these fields. The first case, Diamond v. Chakrabarty, 447 U.S. 303 (1980), pitted the PTO—which had rejected the claims—against microbiologist Ananda Chakrabarty. Chakrabarty had developed a “human-made, genetically engineered bacterium [that was] capable of breaking down multiple components of crude oil.” Id. at 305. The PTO “concluded that § 101 was not intended to cover living things such as these laboratory created microorganisms.” Id. at 306. The Supreme Court, in a 5-4 decision, disagreed. As a general matter, the Court concluded that the text of § 101 sweeps broadly: “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.” Id. at 308. Using legislative history, the Court put a gloss on the text: “The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” Id. at 309 (quoting Senate and House reports). This “made by man” gloss effectively resolved the case in favor of Chakrabarty: “His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ….” Id. The fact that Chakrabarty’s manufacture was also a living organism proved irrelevant to the Supreme Court.

The following year, the Court took up the patentability of a process that included, among other limitations, the use of a digital computer to run a complex computation. The Court had, in the then-recent past, rejected the patentability of two such inventions on the ground that they were tantamount to abstract mathematical algorithms. See Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U. S. 63 (1972). In Diamond v. Diehr, 450 U.S. 175 (1981), by contrast, the
Court followed *Chakrabarty*‘s more expansive approach. And just as in *Chakrabarty*, the vote was a closely divided 5-4. The technology in *Diehr* was a computer-controlled, heated pressure mold for curing synthetic rubber into finished products. The patent claim recited not only the mold, but also the computer controller for the mold and the long-known algorithm the controller used to calculate the best time to stop the cure and open the mold. Claim 1 from the application is set forth in the margin.* The inventors in *Diehr* characterize[d] their contribution to the art to reside in the process of constantly measuring the actual temperature inside the mold. These temperature measurements are then automatically fed into a computer which repeatedly recalculates the cure time by use of the Arrhenius equation. When the recalculated time equals the actual time that has elapsed since the press was closed, the computer signals a device to open the press. According to the respondents, the continuous measuring of the temperature inside the mold cavity, the feeding of this information to a digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press are all new in the art.

* Claim 1 in the *Diehr* application was as follows, with bracketed numbers and letters that I have added to make the limitations/elements of the claim more clear:

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

   [a] providing said computer with a database for said press, including at least,
   
   [1] natural logarithm conversion data (ln),
   [2] the activation energy constant (C) unique to each batch of said compound being molded, and
   [3] a constant (x) dependent upon the geometry of the particular mold of the press,

   [b] initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

   [c] constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

   [d] constantly providing the computer with the temperature (Z),

   [e] repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is

   \[ \ln v = CZ + x \]

   [2] where \( v \) is the total required cure time,

   [f] repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

   [g] opening the press automatically when a said comparison indicates equivalence.
The Court rejected the PTO’s decision to deny patent protection, concluding that a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter. That respondents’ claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed. The respondents’ claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.

Id. at 184. Moreover, its conclusion was “not altered by the fact that, in several steps of the process, a mathematical equation and a programmed digital computer are used.” In the Court’s view, the Diehr inventors did “not seek to patent a mathematical formula. Instead, they sought patent protection for a process of curing synthetic rubber.” Id. at 187. And although “[t]heir process admittedly employ[ed] a well-known mathematical equation, … they d[id] not seek to preempt the use of that equation.” Id.; see also id. at 188 (“Arrhenius’ equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is, at the very least, not barred at the threshold by § 101.”); id. at 192 (“[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.”).

After Diehr, patent applicants sought to locate the dividing line between a patentable practical application of a formula, algorithm, or idea on the one hand, and an unpatentable abstract idea on the other hand, by submitting multiple claims to progressively less and less contextualized algorithms in the patent application. The Supreme Court stayed out of the patentable subject matter area for almost 30 years, allowing the caselaw to develop in the newly created Federal Circuit. The Federal Circuit proved quite receptive to the patentability of computer-implemented processes. For a decade, the Federal Circuit tested patent-eligibility by inquiring whether the claimed invention yields “a useful, concrete, and tangible result.” State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998). A number that represented a real-world item qualified as such a result in the State Street case. Id. at 1373 (holding “that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm”).

In 2006, three members of the Supreme Court expressed concern that the Federal Circuit’s approach to the issue had become too permissive. Justice Breyer, for himself and Justices Stevens and Souter, dissented from the Court’s dismissal of review in a case concerning the patentability of a two-step process for diagnosing a
particular vitamin deficiency. Quoting the Federal Circuit’s “useful, concrete, and tangible result” test for patentable subject matter from *State Street*, Justice Breyer noted that the Supreme Court “has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary.” *Laboratory Corp. v. Metabolite Labs.*, 548 U.S. 124, 136 (2006) (Breyer, J., dissenting from dismissal of certiorari as improvidently granted).

In 2010, the Supreme Court returned to this doctrine. Specifically, in *Bilski v. Kappos*, 561 U.S. 593 (2010), the Court struck down claims to risk-hedging methods as too abstract for patenting. The day after it decided *Bilski*, the Supreme Court vacated the Federal Circuit’s decision in a case called *Prometheus Labs. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009), sending the case back for reconsideration in light of *Bilski*. The Federal Circuit had upheld the medical-diagnostic-method claims at issue in *Mayo* on the ground that practicing the method entailed the physical transformation of matter. Claim 1 of one of the key patents at issue is set forth below:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8 x 10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8 x 10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.


The Federal Circuit, in the post-*Bilski* remand decision, once again held that the claims at issue constituted patentable subject matter. 628 F.3d 1347 (Fed. Cir. 2010). As you will see in a moment, the Supreme Court struck down these patents when it took up the case again in its October 2011 Term.

**Mayo Collaborative Servs. v. Prometheus Labs.**

132 S. Ct. 1289 (2012)

*Breyer, Justice:*

...
ter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could
Newton have patented the law of gravity. Such discoveries are ‘manifestations of ***
nature, free to all men and reserved exclusively to none.’” *Chakrabarty*, 447 U.S. at
309 (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130
(1948)).

“Phenomena of nature, though just discovered, mental processes, and abstract
intellectual concepts are not patentable, as they are the basic tools of scientific and
 technological work.” *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). And monopol-
ization of those tools through the grant of a patent might tend to impede innovation
more than it would tend to promote it.

The Court has recognized, however, that too broad an interpretation of this ex-
clusionary principle could eviscerate patent law. For all inventions at some level em-
body, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract
ideas. Thus, in *Diehr* the Court pointed out that “‘a process is not unpatentable
simply because it contains a law of nature or a mathematical algorithm.’” 450 U.S.
at 187 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)). It added that “an ap-
application of a law of nature or mathematical formula to a known structure or process
may well be deserving of patent protection.” *Diehr*, 450 U.S. at 187. And it emph-
ized Justice Stone’s similar observation in *Mackay Radio & Telegraph Co. v. Radio
Corp. of America*, 306 U.S. 86 (1939):

> “While a scientific truth, or the mathematical expression of it, is not a pa-
tentable invention, a novel and useful structure created with the aid of
knowledge of scientific truth may be.”

450 U.S. at 188 (quoting *Mackay Radio*, 306 U.S. at 94). See also *Funk Brothers,
333 U.S. at 130 (“If there is to be invention from [a discovery of a law of nature], it
must come from the application of the law of nature to a new and useful end”).

Still, as the Court has also made clear, to transform an unpatentable law of
nature into a patent-eligible application of such a law, one must do more than sim-
ply state the law of nature while adding the words “apply it.” See, e.g., *Benson*, 409
U.S. at 71-72.

The case before us lies at the intersection of these basic principles. It concerns
patent claims covering processes that help doctors who use thiopurine drugs to treat
patients with autoimmune diseases determine whether a given dosage level is too
low or too high. The claims purport to apply natural laws describing the relation-
ships between the concentration in the blood of certain thiopurine metabolites and
the likelihood that the drug dosage will be ineffective or induce harmful side-
effects. We must determine whether the claimed processes have transformed these
unpatentable natural laws into patent-eligible applications of those laws. We conclude
that they have not done so and that therefore the processes are not patentable.

Our conclusion rests upon an examination of the particular claims before us in
light of the Court’s precedents. Those cases warn us against interpreting patent stat-
tutes in ways that make patent eligibility “depend simply on the draftsman’s art”
without reference to the “principles underlying the prohibition against patents for
[natural laws].” *Flook*, 437 U.S. at 593. They warn us against upholding patents that
claim processes that too broadly preempt the use of a natural law. Morse, 56 U.S. (15 How.) at 112-120; Benson, 409 U.S. at 71-72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an “inventive concept,” sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. Flook, 437 U.S. at 594; see also Bilski, 130 S. Ct. at 3230 (“[T]he prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment’ or adding ‘insignificant postsolution activity’”) (quoting Diehr, 450 U.S. at 191-92).

We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

A

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn’s disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient’s blood of certain metabolites, including ... 6-thioguanine and its nucleotides (6-TG) and 6-methyl-mercaptopurine (6-MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. See U.S. Patent No. 6,355,623, col. 8, ll. 37-40. (“Previous studies suggested that measurement of 6-MP metabolite levels can be used to predict clinical efficacy and tolerance to azathioprine or 6-MP”) (citing Cuffari, Théorêt, Latour, & Seidman, 6-Mercapto-purine Metabolism in Crohn’s Disease: Correlation with Efficacy and Toxicity, 39 Gut 401 (1996)). But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers’ findings that identified these correlations with some precision.

More specifically, the patents [at issue here]—U.S. Patent No. 6,355,623 and U.S. Patent No. 6,680,302—embody findings that concentrations in a patient’s blood of 6-TG or of 6-MMP metabolite beyond a certain level (400 and 7000 picomoles per 8 × 10⁸ red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6-TG metabolite lower than a certain level (about 230 picomoles per 8 × 10⁸ red blood cells) indicate that the dosage is likely too low to be effective.
The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the ’623 patent, which describes one of the claimed processes ….

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

B

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the ’623 and ’302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per $8 \times 10^8$ for 6-TG, and 5700 pmol per $8 \times 10^8$ for 6-MMP). Prometheus then brought this action claiming patent infringement.

The District Court found that Mayo’s test infringed claim 7 of the ’623 patent. In interpreting the claim, the court accepted Prometheus’ view that the toxicity-risk level numbers in Mayo’s test and the claim were too similar to render the tests significantly different. … The District Court also accepted Prometheus’ view that a doctor using Mayo’s test could violate the patent even if he did not actually alter his treatment decision in the light of the test. …

Nonetheless the District Court ultimately granted summary judgment in Mayo’s favor. The court reasoned that the patents effectively claim natural laws or natural phenomena—namely, the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable.

On appeal, the Federal Circuit reversed. It pointed out that in addition to these natural correlations, the claimed processes specify the steps of (1) “administering a [thiopurine] drug” to a patient and (2) “determining the [resulting metabolite] level.” These steps, it explained, involve the transformation of the human body or of blood taken from the body. Thus, the patents satisfied the Circuit’s “machine or transformation test,” which the court thought sufficient to “confine the patent monopoly within rather definite bounds,” thereby bringing the claims into compliance with §101. 581 F.3d 1336, 1345, 1346-1347 (2009).

Mayo filed a petition for certiorari. We granted the petition, vacated the judgment, and remanded the case for reconsideration in light of Bilski, which clarified that the “machine or transformation test” is not a definitive test of patent eligibility, but only an important and useful clue. On remand the Federal Circuit reaffirmed its earlier conclusion. It thought that the “machine-or-transformation test,” understood merely as an important and useful clue, nonetheless led to the “clear and compelling conclusion *** that the *** claims *** do not encompass laws of nature or preempt natural correlations.” 628 F.3d 1347, 1355 (2010). Mayo again filed a petition for certiorari, which we granted.

II

Prometheus’ patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage
of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that if the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per $8 \times 10^8$ red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no.

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction “apply the law.” Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an “administering” step, a “determining” step, and a “wherein” step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the “administering” step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the “prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.’” *Bilski*, 130 S. Ct. at 3230 (quoting *Diehr*, 450 U.S. at 191-192).

Second, the “wherein” clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision-making (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).
Third, the “determining” step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. ’623 patent, col. 9, ll. 12-65. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. ’623 patent, col. 8, ll. 37-40. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely “conventional or obvious” “[pre]-solution activity” is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Flook*, 437 U.S. at 590; see also *Bilski*, 130 S. Ct. at 3230 (“[T]he prohibition against patenting abstract ideas ‘cannot be circumvented by’ *** adding ‘insignificant post-solution activity’” (quoting *Diehr*, 450 U.S. at 191-92)).

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr*, 450 U.S. at 188. Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

B

1

A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are *Diehr* and *Flook*, two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. …

[In *Diehr* the] Court pointed out that the basic mathematical equation, like a law of nature, was not patentable … [but that] the overall process [was] patent eligible because of the way the additional steps of the process integrated the equation into the [rubber curing] process as a whole. … And so the patentees did not “seek to pre-empt the use of [the] equation,” but sought “only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.” *Diehr*, 450 U.S. at 187. These other steps apparently added to the formula something that in terms of patent law’s objectives had significance—they transformed the process into an inventive application of the formula.

…
... [In *Flook* the Court] characterized the claimed process as doing nothing other than “provide[n] a[n unpatentable] formula for computing an updated alarm limit.” *Flook*, 437 U.S. at 586. ... [T]he other steps in the process did not limit the claim to a particular application. ... “[P]ostsolution activity” that is purely “conventional or obvious” the Court wrote, “can[not] transform an unpatentable principle into a patentable process.” Id. at 589, 590.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in *Diehr* was not so characterized; that in *Flook* was characterized in roughly this way.

... 3

The Court has repeatedly emphasized ... a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in *Morse* the Court set aside as unpatentable Samuel Morse’s general claim for “‘the use of the motive power of the electric or galvanic current ** however developed, for making or printing intelligible characters, letters, or signs, at any distances,’” 56 U.S. (15 How.) at 86. The Court explained:

For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

*Id.* at 113.

Similarly, in *Benson* the Court said that the claims before it were “so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula].” 409 U.S. at 67, 68. In *Bilski* the Court pointed out that to allow “petitioners to patent risk hedging would pre-empt use of this approach in all fields.” 130 S. Ct. at 3231. And in *Flook* the Court expressed concern that the claimed process was simply “a formula for computing an updated alarm limit,” which might “cover a broad range of potential uses.” 437 U.S. at 586.

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their dis-
covery, those laws and principles, considered generally, are “the basic tools of scientific and technological work.” Benson, 409 U.S. at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to “apply the natural law,” or otherwise forecloses more future invention than the underlying discovery could reasonably justify. See generally Lemley, Risch, Sichelman, & Wagner, Life After Bilski, 63 Stan. L. Rev. 1315 (2011) (arguing that §101 reflects this kind of concern); see also C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012) (“One problem with [process] patents is that the more abstractly their claims are stated, the more difficult it is to determine precisely what they cover. They risk being applied to a wide range of situations that were not anticipated by the patentee”); W. Landes & R. Posner, The Economic Structure of Intellectual Property Law 305-306 (2003) (The exclusion from patent law of basic truths reflects “both *** the enormous potential for rent seeking that would be created if property rights could be obtained in them and *** the enormous transaction costs that would be imposed on would-be users [of those truths]”).

The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor’s subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo’s test), that combine Prometheus’ correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The “determining” step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent.

III

…

[Finally], Prometheus, supported by several amici, argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of
nature, is expensive; it “ha[s] made the United States the world leader in this field”; and it requires protection. Brief for Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if “claims to exclusive rights over the body’s natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care.” Brief for American College of Medical Genetics et al. as Amici Curiae 7; see also App. to Brief for Association Internationale pour la Protection de la Propriété Intellectuelle et al. as Amici Curiae A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law’s general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another. See Bohannan & Hovenkamp, Creation without Restraint at 98-100.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U.S. C. §§ 161-164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

*   *   *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. ...
After Mayo, the Supreme Court vacated and remanded a case to the Federal Circuit for reconsideration. That case, Myriad Genetics, relates to whether isolated, purified DNA molecules are patentable subject matter under § 101. On remand, the Federal Circuit divided on the question and, in the October 2012 Term, the Supreme Court took up the Myriad Genetics case again.

**Association for Molecular Pathology v. Myriad Genetics, Inc.**

133 S. Ct. 2107 (2013)

Thomas, Justice:

Respondent Myriad Genetics, Inc. (Myriad), discovered the precise location and sequence of two human genes, mutations of which can substantially increase the risks of breast and ovarian cancer. Myriad obtained a number of patents based upon its discovery. This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. ...

I

A

Genes form the basis for hereditary traits in living organisms. The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA, which takes the shape of the familiar “double helix” ... Each “cross-bar” in the DNA helix consists of two chemically joined nucleotides. The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide: A pairs with T; C pairs with G. The nucleotide cross-bars are chemically connected to a sugar-phosphate backbone that forms the outside framework of the DNA helix. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as “exons.” Nucleotides that do not code for amino acids, in contrast, are known as “introns.”

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used as a template to create a complementary ribonucleic acid (RNA) strand. The nucleotides on the DNA strand pair naturally with their counterparts, with the exception that RNA uses the nucleotide base uracil (U) instead of thymine (T). Transcription results in a single strand RNA molecule, known as pre-RNA, whose nucleotides form an inverse image of the DNA strand from which it was created. Pre-RNA still contains nucleotides corresponding to both the exons and introns in the DNA mol-
ecule. The pre-RNA is then naturally “spliced” by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production.

DNA’s informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well known laboratory methods. These methods allow scientists to isolate specific segments of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used. It is also possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The result is the inverse of the mRNA’s inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as complementary DNA (cDNA).

Changes in the genetic sequence are called mutations. Mutations can be as small as the alteration of a single nucleotide—a change affecting only one letter in the genetic code. Such small-scale changes can produce an entirely different amino acid or can end protein production altogether. Large changes, involving the deletion, rearrangement, or duplication of hundreds or even millions of nucleotides, can result in the elimination, misplacement, or duplication of entire genes. Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical breakthroughs.

This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can dramatically increase an individual’s risk of developing breast and ovarian cancer. The average American woman has a 12- to 13-% risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 % for breast cancer and between 20 and 50 % for ovarian cancer. Before Myriad’s discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman’s risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.

Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million. Association for Molecular Pathology v. United States Patent and Trademark Office, 689 F.3d 1303, 1328 (Fed. Cir. 2012). Within those chromosomes, the BRCA1 and BRCA2 genes are each
about 80,000 nucleotides long. If just exons are counted, the BRCA1 gene is only about 5,500 nucleotides long; for the BRCA2 gene, that number is about 10,200. *Id.* Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence. That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient’s BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. Nine composition claims from three of those patents are at issue in this case. Claims 1, 2, 5, and 6 from the ’282 patent are representative. The first claim asserts a patent on “[a]n isolated DNA coding for a BRCA1 polypeptide,” which has “the amino acid sequence set forth in SEQ ID NO:2.” SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes. Put differently, claim 1 [is] a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO:2.

Claim 2 of the ’282 patent operates similarly. It claims “[t]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.” Like SEQ ID NO:2, SEQ ID NO:1 sets forth a long list of data, in this instance the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1. Importantly, SEQ ID NO:1 lists only the cDNA exons in the BRCA1 gene, rather than a full DNA sequence containing both exons and introns. As a result, the Federal Circuit recognized that claim 2 asserts a patent on the cDNA nucleotide sequence listed in SEQ ID NO:1, which codes for the typical BRCA1 gene.

Claim 5 of the ’282 patent claims a subset of the data in claim 1. In particular, it claims “[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1.” The practical effect of claim 5 is to assert a patent on any series of 15 nucleotides that exist in the typical BRCA1 gene. Because the BRCA1 gene is thousands of nucleotides long, even BRCA1 genes with substantial mutations are likely to contain at least one segment of 15 nucleotides that correspond to the typical BRCA1 gene. Similarly, claim 6 of the ’282 patent claims “[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2.” This claim operates similarly to claim 5, except that it references the cDNA-based claim 2. The remaining claims at issue are similar, though several list common mutations rather than typical BRCA1 and BRCA2 sequences.

C

Myriad’s patents would, if valid, give it the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual’s genome. The patents would also give Myriad the exclusive right to synthetically create BRCA cDNA. In Myriad’s view, manipulating BRCA DNA in either of these fashions triggers its “right to exclude others from making” its patented composition of matter under the Patent Act. 35 U.S.C. § 154(a)(1).

But isolation is necessary to conduct genetic testing, and Myriad was not the only entity to offer BRCA testing after it discovered the genes. The University of Pennsylvania’s Genetic Diagnostic Laboratory (GDL) and others provided genetic
testing services to women. Petitioner Dr. Harry Ostrer, then a researcher at New
York University School of Medicine, routinely sent his patients’ DNA samples to
GDL for testing. After learning of GDL’s testing and Ostrer’s activities, Myriad sent
letters to them asserting that the genetic testing infringed Myriad’s patents. In re-
sponse, GDL agreed to stop testing and informed Ostrer that it would no longer
accept patient samples. Myriad also filed patent infringement suits against other enti-
ties that performed BRCA testing, resulting in settlements in which the defendants
agreed to cease all allegedly infringing activity. Myriad, thus, solidified its position as
the only entity providing BRCA testing.

Some years later, petitioner Ostrer, along with medical patients, advocacy
groups, and other doctors, filed this lawsuit seeking a declaration that Myriad’s
patents are invalid under 35 U.S.C. § 101. … The District Court … granted sum-
mary judgment to petitioners on the composition claims at issue in this case based
on its conclusion that Myriad’s claims, including claims related to cDNA, were in-
valid because they covered products of nature. …

… [T]he Federal Circuit affirmed the District Court in part and reversed in
part, with each member of the panel writing separately. …

… [T]he court held that both isolated DNA and cDNA were patent eligible
under § 101. The central dispute among the panel members was whether the act of
isolating DNA—separating a specific gene or sequence of nucleotides from the rest
of the chromosome—is an inventive act that entitles the individual who first isolates
it to a patent. Each of the judges on the panel had a different view on that question.
Judges Lourie and Moore agreed that Myriad’s claims were patent eligible under
§ 101 but disagreed on the rationale. Judge Lourie relied on the fact that the entire
DNA molecule is held together by chemical bonds and that the covalent bonds at
both ends of the segment must be severed in order to isolate segments of DNA. …
Judge Lourie found this chemical alteration to be dispositive, because isolating a
particular strand of DNA creates a nonnaturally occurring molecule, even though
the chemical alteration does not change the information-transmitting quality of the
DNA. …

Judge Moore concurred in part but did not rely exclusively on Judge Lourie’s
conclusion that chemically breaking covalent bonds was sufficient to render isolated
DNA patent eligible. Instead, Judge Moore also relied on the United States Patent
and Trademark Office’s (PTO) practice of granting such patents and on the reliance
interests of patent holders. …

Finally, Judge Bryson concurred in part and dissented in part, concluding that
isolated DNA is not patent eligible. … [H]e relied on the fact that “[t]he nucleotide
sequences of the claimed molecules are the same as the nucleotide sequences found
in naturally occurring human genes.” [689 F.3d] at 1355. Judge Bryson then con-
cluded that genetic “structural similarity dwarfs the significance of the structural dif-
fferences between isolated DNA and naturally occurring DNA, especially where the
structural differences are merely ancillary to the breaking of covalent bonds, a pro-
cess that is itself not inventive.” Id. …
Although the judges expressed different views concerning the patentability of isolated DNA, all three agreed that patent claims relating to cDNA met the patent eligibility requirements of § 101. …

II

A

Section 101 of the Patent Act provides: “Whoever invents or discovers any new and useful * * * composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101.

We have “long held that this provision contains an important implicit exception[;] Laws of nature, natural phenomena, and abstract ideas are not patentable.” Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012). Rather, “they are the basic tools of scientific and technological work” that lie beyond the domain of patent protection. Id. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them.” Id. at 1301. This would be at odds with the very point of patents, which exist to promote creation. Diamond v. Chakrabarty, 447 U. S. 303, 309 (1980) (Products of nature are not created, and “manifestations *** of nature [are] free to all men and reserved exclusively to none”).

The rule against patents on naturally occurring things is not without limits, however, for “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and “too broad an interpretation of this exclusionary principle could eviscerate patent law.” Mayo, 132 S. Ct. at 1293. As we have recognized before, patent protection strikes a delicate balance between creating “incentives that lead to creation, invention, and discovery” and “imped[ing] the flow of information that might permit, indeed spur, invention.” Id. at 1305. We must apply this well-established standard to determine whether Myriad’s patents claim any “new and useful *** composition of matter,” §101, or instead claim naturally occurring phenomena.

B

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in Chakrabarty is central to this inquiry. In Chakrabarty, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U.S. at 305 & n.1. The Court held that the modified bacterium was patentable. It explained that the patent claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having
a distinctive name, character [and] use.” *Id.* at 309-310 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature,” 447 U.S. at 310, due to the additional plasmids and resultant “capacity for degrading oil.” *Id.* at 305 n.1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. *Id.* at 128-129. The ability of the bacteria to fix nitrogen was well known, and farmers commonly “inoculated” their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. *Id.* at 129-130. Upon learning that several nitrogen-fixing bacteria did not inhibit each other, however, the patent applicant combined them into a single inoculant and obtained a patent. *Id.* at 130. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. *Id.* at 132. His patent claim thus fell squarely within the law of nature exception. So do Myriad’s. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes “new *** composition[s] of matter,” § 101, that are patent eligible.

Indeed, Myriad’s patent descriptions highlight the problem with its claims. For example, a section of the ’282 patent’s Detailed Description of the Invention indicates that Myriad found the location of a gene associated with increased risk of breast cancer and identified mutations of that gene that increase the risk. In subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome 17. The ’473 and ’492 patents contain similar language as well. Many of Myriad’s patent descriptions simply detail the “iterative process” of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought. Myriad seeks to import these extensive research efforts into the § 101 patent eligibility inquiry. But extensive effort alone is insufficient to satisfy the demands of § 101.

Nor are Myriad’s claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring mole-

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6 Myriad first identified groups of relatives with a history of breast cancer (some of whom also had developed ovarian cancer); because these individuals were related, scientists knew that it was more likely that their diseases were the result of genetic predisposition rather than other factors. Myriad compared sections of their chromosomes, looking for shared genetic abnormalities not found in the general population. It was that process which eventually enabled Myriad to determine where in the genetic sequence the BRCA1 and BRCA2 genes reside.
cule. Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad’s patent claims on entire genes (such as claims 1 and 2 of the ’282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule “invented” by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

Finally, Myriad argues that the PTO’s past practice of awarding gene patents is entitled to deference, citing J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124 (2001). We disagree. J.E.M. held that new plant breeds were eligible for utility patents under § 101 notwithstanding separate statutes providing special protections for plants, see 7 U.S.C. § 2321 et seq. (Plant Variety Protection Act); 35 U.S.C. §§ 161-164 (Plant Patent Act of 1930). After analyzing the text and structure of the relevant statutes, the Court mentioned that the Board of Patent Appeals and Interferences had determined that new plant breeds were patent eligible under § 101 and that Congress had recognized and endorsed that position in a subsequent Patent Act amendment. 534 U.S. at 144-145 (citing In re Hibberd, 227 USPQ 443 (1985) and 35 U.S.C. § 119(f)). In this case, however, Congress has not endorsed the views of the PTO in subsequent legislation. …

Further undercutting the PTO’s practice, the United States argued in the Federal Circuit and in this Court that isolated DNA was not patent eligible under § 101, Brief for United States as Amicus Curiae 20-33, and that the PTO’s practice was not “a sufficient reason to hold that isolated DNA is patent-eligible.” Id. at 26. These concessions [by the Solicitor General of the United States, on behalf of the United States,] weigh against deferring to the PTO’s determination.

C

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.8 Petitioners concede that cDNA differs from natural DNA in that “the non-coding re-

8 Some viruses rely on an enzyme called reverse transcriptase to reproduce by copying RNA into cDNA. In rare instances, a side effect of a viral infection of a cell can be the random incorporation of fragments of the resulting cDNA, known as a pseudogene, into the genome. Such pseudogenes … are not expressed in protein creation because they lack genetic sequences to direct protein expression. See J. Watson et al., Molecular Biology of the Gene 142, 144 fig. 7-5 (6th ed. 2008). … The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.
gions have been removed.” They nevertheless argue that cDNA is not patent eligible because “[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician.” That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a “product of nature” and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.9

III

It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad’s patents “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,” 702 F. Supp. 2d at 202-203, and are not at issue in this case.

Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.” 689 F.3d at 1349.

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.

…

9 We express no opinion whether cDNA satisfies the other statutory requirements of patentability. See, e.g., 35 U.S.C. §§ 102, 103, and 112.
Computed-Implemented Processes


In the most recent Supreme Court decision about patentable subject matter, issued in June 2014, the Court synthesized its approaches in Bilski and Mayo into a unified two-step analysis.

Alice Corp. v. CLS Bank Int’l
134 S. Ct. 2347 (June 19, 2014)

Thomas, Justice:

The patents at issue in this case disclose a computer-implemented scheme for mitigating “settlement risk” (i.e., the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary. The question presented is whether these claims are patent eligible under 35 U.S.C. § 101, or are instead drawn to a patent-ineligible abstract idea. We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention. We therefore affirm the judgment of the United States Court of Appeals for the Federal Circuit.

I

A

Petitioner Alice Corporation is the assignee of several patents that disclose schemes to manage certain forms of financial risk. According to the specification largely shared by the patents, the invention “enabl[es] the management of risk relating to specified, yet unknown, future events.” The specification further explains that the “invention relates to methods and apparatus, including electrical computers and data processing systems applied to financial matters and risk management.”

The claims at issue relate to a computerized scheme for mitigating “settlement risk”—i.e., the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The intermediary creates “shadow” credit and debit records

2 The parties agree that claim 33 of [U.S. Patent No. 5,970, 479] is representative … . Claim 33 recites:

A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:

(a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;

(b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
(i.e., account ledgers) that mirror the balances in the parties’ real-world accounts at “exchange institutions” (e.g., banks). The intermediary updates the shadow records in real time as transactions are entered, allowing “only those transactions for which the parties’ updated shadow records indicate sufficient resources to satisfy their mutual obligations.” 717 F.3d 1269, 1285 (Fed. Cir. 2013) (Lourie, J., concurring). At the end of the day, the intermediary instructs the relevant financial institutions to carry out the “permitted” transactions in accordance with the updated shadow records, thus mitigating the risk that only one party will perform the agreed-upon exchange.

In sum, the patents in suit claim (1) the foregoing method for exchanging obligations (the method claims), (2) a computer system configured to carry out the method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well.

B

Respondents CLS Bank International and CLS Services Ltd. (together, CLS Bank) operate a global network that facilitates currency transactions. In 2007, CLS Bank filed suit against petitioner, seeking a declaratory judgment that the claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. Following this Court’s decision in Bilski v. Kappos, 561 U.S. 593 (2010), the parties filed cross-motions for summary judgment on whether the asserted claims are eligible for patent protection under 35 U.S.C. § 101. The District Court held that all of the claims are patent ineligible because they are directed to the [same] abstract idea ... .

A divided panel of the United States Court of Appeals for the Federal Circuit reversed, holding that it was not “manifestly evident” that petitioner’s claims are directed to an abstract idea. 685 F.3d 1341, 1352, 1356 (Fed. Cir. 2012). The Federal Circuit granted rehearing en banc, vacated the panel opinion, and affirmed the judgment of the District Court in a one-paragraph per curiam opinion. 717 F.3d at 1273. Seven of the ten participating judges agreed that petitioner’s method and

(c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party’s shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and

(d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.
media claims are patent ineligible. With respect to petitioner’s system claims, the en banc Federal Circuit affirmed the District Court’s judgment by an equally divided vote.

Writing for a five-member plurality, Judge Lourie concluded that all of the claims at issue are patent ineligible. In the plurality’s view, under this Court’s decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012), a court must first “identify[y] the abstract idea represented in the claim,” and then determine “whether the balance of the claim adds ‘significantly more.’” 717 F.3d at 1286. The plurality concluded that petitioner’s claims “draw on the abstract idea of reducing settlement risk by effecting trades through a third-party intermediary,” and that the use of a computer to maintain, adjust, and reconcile shadow accounts added nothing of substance to that abstract idea.

II

Section 101 of the Patent Act defines the subject matter eligible for patent protection. …

“We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013). We have interpreted § 101 and its predecessors in light of this exception for more than 150 years. O’Reilly v. Morse, 56 U.S. (15 How.) 62, 112-120 (1854); Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174-175 (1853).

We have described the concern that drives this exclusionary principle as one of pre-emption. See, e.g., Bilski, 561 U.S. at 611-612 (upholding the patent “would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea”). Laws of nature, natural phenomena, and abstract ideas are “the basic tools of scientific and technological work.” Myriad, 133 S. Ct. at 2116. “[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,” thereby thwarting the primary object of the patent laws. Mayo, 132 S. Ct. at 1293; see U.S. Const., Art. I, § 8, cl. 8 (Congress “shall have Power *** To promote the Progress of Science and useful Arts”). We have “repeatedly emphasized this *** concern that patent law not inhibit further discovery by improperly tying up the future use” of these building blocks of human ingenuity. Mayo, 132 S. Ct. at 1301.

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. Mayo, 132 S. Ct. at 1293. At some level, “all inventions *** embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” Id. Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See Diamond v. Diehr, 450 U.S. 175, 187 (1981). “[A]plication[s]” of such concepts “to a new and useful end,” we have said, remain eligible for patent protection. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

Accordingly, in applying the § 101 exception, we must distinguish between patents that claim the “buildin[g] block[s]” of human ingenuity and those that inte-
grate the building blocks into something more, *Mayo*, 132 S. Ct. at 1303, thereby “transform[ing]” them into a patent-eligible invention, *id.* at 1294. The former “would risk disproportionately tying up the use of the underlying” ideas, *id.*, and are therefore ineligible for patent protection. The latter pose no comparable risk of preemption, and therefore remain eligible for the monopoly granted under our patent laws.

III

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Id.* at 1296-97. If so, we then ask, “[w]hat else is there in the claims before us?” *Id.* at 1297. To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the claim” into a patent-eligible application. *Id.* 1297-98. We have described step two of this analysis as a search for an “inventive concept”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Id.* at 1294.3

A

We must first determine whether the claims at issue are directed to a patent-ineligible concept. We conclude that they are: These claims are drawn to the abstract idea of intermediated settlement.

The “abstract ideas” category embodies “the longstanding rule that ‘[a]n idea of itself is not patentable.’” *Benson*, 409 U.S. at 67. In *Benson*, for example, this Court rejected as ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, holding that the claimed patent was “in practical effect *** a patent on the algorithm itself.” 409 U.S. at 71-72. And in *Parker v. Flook*, 437 U.S. 584, 594-595 (1978), we held that a mathematical formula for computing “alarm limits” in a catalytic conversion process was also a patent-ineligible abstract idea.

We most recently addressed the category of abstract ideas in *Bilski v. Kappos*, 561 U.S. 593 (2010). …

“[A]ll members of the Court agree[d]” that the patent at issue in *Bilski* claimed an “abstract idea.” *Id.* at 609; see also *id.* at 619 (Stevens, J., concurring in the judgment). Specifically, the claims described “the basic concept of hedging, or protecting against risk.” *Id.* at 611. The Court explained that “‘[h]edging is a fun-
damental economic practice long prevalent in our system of commerce and taught in
any introductory finance class.” Id. “The concept of hedging” as recited by the
claims in suit was therefore a patent-ineligible “abstract idea, just like the algorithms
at issue in Benson and Flook.” Id.

It follows from our prior cases, and Bilski in particular, that the claims at issue
here are directed to an abstract idea. Petitioner’s claims involve a method of ex-
changing financial obligations between two parties using a third-party intermediary
to mitigate settlement risk. The intermediary creates and updates “shadow” records
to reflect the value of each party’s actual accounts held at “exchange institutions,”
thereby permitting only those transactions for which the parties have sufficient re-
sources. At the end of each day, the intermediary issues irrevocable instructions to
the exchange institutions to carry out the permitted transactions.

On their face, the claims before us are drawn to the concept of intermediated
settlement, i.e., the use of a third party to mitigate settlement risk. Like the risk
hedging in Bilski, the concept of intermediated settlement is “a fundamental eco-
nomic practice long prevalent in our system of commerce.” Id.; see, e.g., Emery,
Speculation on the Stock and Produce Exchanges of the United States, in 7 Studies in
History, Economics and Public Law 283, 346-356 (1896) (discussing the use of a
“clearing-house” as an intermediary to reduce settlement risk). The use of a third-
party intermediary (or “clearing house”) is also a building block of the modern
economy. See, e.g., Yadav, The Problematic Case of Clearinghouses in Complex Mar-
Institutions 103-104 (3d ed. 2012). Thus, intermediated settlement, like hedging, is
an “abstract idea” beyond the scope of § 101.

Petitioner acknowledges that its claims describe intermediated settlement, see
Brief for Petitioner 4, but rejects the conclusion that its claims recite an “abstract
idea.” Drawing on the presence of mathematical formulas in some of our abstract-
ideas precedents, petitioner contends that the abstract-ideas category is confined to
“preexisting, fundamental truth[s]” that “exist[s] in principle apart from any human
action.” Id. at 23, 26 (quoting Mayo, 132 S. Ct. at 1297).

Bilski belies petitioner’s assertion. The concept of risk hedging we identified as
an abstract idea in that case cannot be described as a “preexisting, fundamental
truth.” The patent in Bilski simply involved a “series of steps instructing how to
hedge risk.” 561 U.S. at 599. Although hedging is a longstanding commercial prac-
tice, id. at 599, it is a method of organizing human activity, not a “truth” about the
natural world “that has always existed,” Brief for Petitioner 22. One of the claims in
Bilski reduced hedging to a mathematical formula, but the Court did not assign any
special significance to that fact, much less the sort of talismanic significance petitio-
er claims. Instead, the Court grounded its conclusion that all of the claims at issue
were abstract ideas in the understanding that risk hedging was a “fundamental eco-
nomic practice.” 561 U.S. at 611.

In any event, we need not labor to delimit the precise contours of the “abstract
ideas” category in this case. It is enough to recognize that there is no meaningful
distinction between the concept of risk hedging in Bilski and the concept of inter-
mediated settlement at issue here. Both are squarely within the realm of “abstract ideas” as we have used that term.

B

Because the claims at issue are directed to the abstract idea of intermediated settlement, we turn to the second step in Mayo’s framework. We conclude that the method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention.

1

At Mayo step two, we must examine the elements of the claim to determine whether it contains an “inventive concept” sufficient to “transform” the claimed abstract idea into a patent-eligible application. 132 S. Ct. 1294, 1298. A claim that recites an abstract idea must include “additional features” to ensure “that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].” Id. 1297. Mayo made clear that transformation into a patent-eligible application requires “more than simply stat[ing] the [abstract idea] while adding the words ‘apply it.’” Id. 1294.

Mayo itself is instructive. The patents at issue in Mayo claimed a method for measuring metabolites in the bloodstream in order to calibrate the appropriate dosage of thiopurine drugs in the treatment of autoimmune diseases. Id. at 1295. The respondent in that case contended that the claimed method was a patent-eligible application of natural laws that describe the relationship between the concentration of certain metabolites and the likelihood that the drug dosage will be harmful or ineffective. But methods for determining metabolite levels were already “well known in the art,” and the process at issue amounted to “nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.” Id. at 1297-98. “Simply appending conventional steps, specified at a high level of generality,” was not “enough” to supply an “inventive concept.” Id. at 1300, 1297, 1294.

The introduction of a computer into the claims does not alter the analysis at Mayo step two. In Benson, for example, we ... “held that simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle.” Mayo, 132 S. Ct. at 1301 (citing Benson, 409 U.S. at 64).

Flook is to the same effect. ... In holding that the process was patent ineligible, we rejected the argument that “implement[ing] a principle in some specific fashion” will “automatically fall[] within the patentable subject matter of § 101.” Id. at 593. Thus, “Flook stands for the proposition that the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment.” Bilski, 561 U.S. at 610-611.

In Diehr, 450 U.S. 175, by contrast, we held that a computer-implemented process for curing rubber was patent eligible, but not because it involved a computer. The claim employed a “well-known” mathematical equation, but it used that equation in a process designed to solve a technological problem in “conventional industry practice.” Id. at 177, 178. The invention in Diehr used a “thermocouple”
to record constant temperature measurements inside the rubber mold—something “the industry ha[d] not been able to obtain.” *Id.* at 178 & n.3. The temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation. *Id.* at 178-79. These additional steps, we recently explained, “transformed the process into an inventive application of the formula.” *Mayo*, 132 S. Ct. at 1299. In other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.

These cases demonstrate that the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea “while adding the words ‘apply it’” is not enough for patent eligibility. *Mayo*, 132 S. Ct. at 1294. Nor is limiting the use of an abstract idea “to a particular technological environment.” *Bilski*, 561 U.S. at 610-11. Stating an abstract idea while adding the words “apply it with a computer” simply combines those two steps, with the same deficient result. Thus, if a patent’s recitation of a computer amounts to a mere instruction to “implement[ ]” an abstract idea “on *** a computer,” *Mayo*, 132 S. Ct. at 1301, that addition cannot impart patent eligibility. This conclusion accords with the preemption concern that undergirds our § 101 jurisprudence. Given the ubiquity of computers, wholly generic computer implementation is not generally the sort of “additional feature” that provides any “practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.” *Mayo*, 132 S. Ct. at 1297.

The fact that a computer “necessarily exist[s] in the physical, rather than purely conceptual, realm,” Brief for Petitioner 39, is beside the point. There is no dispute that a computer is a tangible system (in § 101 terms, a “machine”), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the § 101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility “depend simply on the draftsman’s art,” *Flook*, 437 U.S. at 593, thereby eviscerating the rule that “[l]aws of nature, natural phenomena, and abstract ideas are not patentable,” *Myriad*, 133 S. Ct. at 2116.

The representative method claim in this case recites the following steps: (1) “creating” shadow records for each counterparty to a transaction; (2) “obtaining” start-of-day balances based on the parties’ real-world accounts at exchange institutions; (3) “adjusting” the shadow records as transactions are entered, allowing only those transactions for which the parties have sufficient resources; and (4) issuing irrevocable end-of-day instructions to the exchange institutions to carry out the permitted transactions. Petitioner principally contends that the claims are patent eligible because these steps “require a substantial and meaningful role for the computer.” Brief for Petitioner 48. As stipulated, the claimed method requires the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions; in other words, “[t]he computer is itself the intermediary.” *Id.*
In light of the foregoing, the relevant question is whether the claims here do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. They do not.

Taking the claim elements separately, the function performed by the computer at each step of the process is “[p]urely conventional.” *Mayo*, 132 S. Ct. at 1298. Using a computer to create and maintain “shadow” accounts amounts to electronic recordkeeping—one of the most basic functions of a computer. *See e.g., Benson*, 409 U.S. at 65 (noting that a computer “operates *** upon both new and previously stored data”). The same is true with respect to the use of a computer to obtain data, adjust account balances, and issue automated instructions; all of these computer functions are “well-understood, routine, conventional activ[ies]” previously known to the industry. *Mayo*, 132 S. Ct. 1298. In short, each step does no more than require a generic computer to perform generic computer functions.

Considered “as an ordered combination,” the computer components of petitioner’s method “ad[d] nothing *** that is not already present when the steps are considered separately.” *Id.* Viewed as a whole, petitioner’s method claims simply recite the concept of intermediated settlement as performed by a generic computer. *See 717 F.3d at 1286* (Lourie, J., concurring) (noting that the representative method claim “lacks any express language to define the computer’s participation”). The method claims do not, for example, purport to improve the functioning of the computer itself. *See id.* (“There is no specific or limiting recitation of *** improved computer technology ***.”); *Brief for United States as Amicus Curiae* 28-30. Nor do they effect an improvement in any other technology or technical field. *See e.g., Diehr*, 450 U.S. at 177-178. Instead, the claims at issue amount to “nothing significantly more” than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer. *Mayo*, 132 S. Ct. 1298. Under our precedents, that is not “enough” to transform an abstract idea into a patent-eligible invention. *Id.* at 1297.

C

Petitioner’s claims to a computer system and a computer-readable medium fail for substantially the same reasons. Petitioner conceded below that its media claims rise or fall with its method claims. As to its system claims, petitioner emphasizes that those claims recite “specific hardware” configured to perform “specific computerized functions.” *Brief for Petitioner* 53. But what petitioner characterizes as specific hardware—a “data processing system” with a “communications controller” and “data storage unit,” for example—is purely functional and generic. Nearly every computer will include a “communications controller” and “data storage unit” capable of performing the basic calculation, storage, and transmission functions required by the method claims. *See 717 F.3d at 1290* (Lourie, J., concurring). As a result, none of the hardware recited by the system claims “offers a meaningful limitation beyond generally linking ‘the use of the [method] to a particular technological environment,’ that is, implementation via computers.” *Id.* at 1291 (quoting *Bilski*, 561 U.S. at 610-611).

Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic
computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long “warn[ed] *** against” interpreting § 101 “in ways that make patent eligibility ‘depend simply on the draftsman’s art.’” Mayo, 132 S. Ct. 1294 (quoting Flook, 437 U.S. at 593); see Flook, 437 U.S. at 590 (“The concept of patentable subject matter under § 101 is not ‘like a nose of wax which may be turned and twisted in any direction *** .’”) (quoting White v. Dunbar, 119 U.S. 47, 51 (1886)). Holding that the system claims are patent eligible would have exactly that result.

Because petitioner’s system and media claims add nothing of substance to the underlying abstract idea, we hold that they too are patent ineligible under § 101.

... 

Clones

In re Roslin Institute (Edinburgh)

750 F.3d 1333 (Fed. Cir. 2014)

Dyk, Judge:

The Roslin Institute of Edinburgh, Scotland, is the assignee of U.S. Patent Application No. 09/225,233 [originally filed Jan. 4, 1999,] and appeals from a final decision of the Patent Trial and Appeal Board. The Board held that all of Roslin’s pending claims ... were unpatentable subject matter under 35 U.S.C. § 101. The Board also rejected Roslin’s claims as anticipated and obvious ... . We affirm the Board’s rejection of the claims under § 101.

Background

On July 5, 1996, Keith Henry Stockman Campbell and Ian Wilmut successfully produced the first mammal ever cloned from an adult somatic cell: Dolly the Sheep. A clone is an identical genetic copy of a cell, cell part, or organism.

The cloning method Campbell and Wilmut used to create Dolly constituted a breakthrough in scientific discovery. Known as somatic cell nuclear transfer, this process involves removing the nucleus of a somatic cell and implanting that nucleus into an enucleated (i.e., without a nucleus) oocyte. A somatic cell is any body cell other than gametes (egg or sperm). An oocyte is a female gametocyte (an egg cell prior to maturation), and a nucleus is the organelle that holds a cell’s genetic material (its DNA). Often referred to as “adult” cells, somatic cells are differentiated, i.e., they are specialized to perform specific functions. For example, liver, heart, and muscle cells are all differentiated, somatic cells.

To create Dolly, Campbell and Wilmut fused the nucleus of an adult, somatic mammary cell with an enucleated oocyte. Specifically, Campbell and Wilmut found that if the donor somatic cell is arrested in the stage of the cell cycle where it is dormant and non-replicating (the quiescent phase) prior to nuclear transfer, the resulting fused cell will develop into a reconstituted embryo. Once the nucleus of a somatic donor cell is removed, that nucleus is fused with an oocyte, which develops into an embryo. The embryo can then be implanted into a surrogate mammal,
where it develops into a baby animal. The resulting cloned animal is an exact genetic replica of the adult mammal from which the somatic cell nucleus was taken.

Campbell and Wilmut obtained a patent on the somatic method of cloning mammals, which has been assigned to Roslin. See U.S. Patent No. 7,514,258. The ‘258 patent is not before us in this appeal. Instead, the dispute here concerns the PTO’s rejection of Campbell’s and Wilmut’s claims to the clones themselves, set forth in the ’233 application, titled Quiescent Cell Populations for Nuclear Transfer.

The ’233 application claims the products of Campbell’s and Wilmut’s cloning method: cattle, sheep, pigs, and goats. Claims 155 and 164 are representative:

155. A live-born clone of a pre-existing, nonembryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.

164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.

As the Board described, “[c]laims 156-159 depend from claim 155 and further specify that the claimed clones are limited to clones of cattle, sheep, pigs, and goats, respectively.”

On November 10, 2008, the examiner issued a nonfinal rejection of Campbell’s and Wilmut’s patent claims because she found that they were directed to nonstatutory subject matter under 35 U.S.C. § 101 as well as anticipated and obvious … . On February 7, 2013, the Board affirmed the examiner’s rejection of all of Campbell’s and Wilmut’s claims. Although the Board acknowledged that the claimed clones “may be called a composition of matter or a manufacture” as required by § 101, it concluded that the claimed subject matter was ineligible for patent protection under § 101 because it constituted a natural phenomenon that did not possess “markedly different characteristics than any found in nature.”

Discussion

I

An inventor may obtain a patent for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101; see Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010). An invention that falls within one of these categories of patentable subject matter may still be ineligible for patent protection if it meets one of three exceptions. Laws of nature, natural phenomena, and abstract ideas are not eligible for patent protection. See Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012); Bilski, 130 S. Ct. at 3225; Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

Even before the Supreme Court’s recent decision in Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013), the Court’s opinions in Chakrabarty and Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), made clear that naturally occurring organisms are not patentable.

In Funk Bros., the Supreme Court considered a patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants extract nitrogen from the air and fix it in soil. 333 U.S. at 128-29. The Court concluded that this
mixture of bacteria strains was not patent eligible because the patentee did not alter the bacteria in any way. Id. at 132 (“[T]here is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.”). Critically, in Funk Bros., the Court explained:

[w]e do not have presented the question whether the methods of selecting and testing the noninhibitive strains are patentable. We have here only product claims. [The patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. Id. at 130. Thus, while the method of selecting the strains of bacteria might have been patent eligible, the natural organism itself—the mixture of bacteria—was un-patentable because its “qualities are the work of nature” unaltered by the hand of man. Id.

In Chakrabarty, the Court clarified the scope of Funk. The patent at issue in Chakrabarty claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil. 447 U.S. at 305. The patent applicant created this non-naturally occurring bacterium by adding four plasmids to a specific strain of bacteria. Id. at 305 n.1. Overturning the Board’s rejections, the Court held that the modified bacterium was patentable because it was “new” with “markedly different characteristics from any found in nature and one having the potential for significant utility.” Id. at 310 (emphasis added). As the Court explained, the patentee’s “discovery is not nature’s handiwork, but his own.” Id.

Accordingly, discoveries that possess “markedly different characteristics from any found in nature,” id., are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. Id. at 309; see also In re Beineke, 690 F.3d 1344, 1352 (Fed. Cir. 2012) (holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not “in any way the result of [the patent applicant’s] creative efforts or indeed anyone’s creative efforts.”).

More recently, in Myriad, the Court held that claims on two naturally occurring, isolated genes (BRCA1 and BRCA2), which can be examined to determine whether a person may develop breast cancer, were invalid under § 101. 133 S. Ct. at 2112-13, 2117-18. The Supreme Court concluded that the BRCA genes themselves were unpatentable products of nature.

While Roslin does not dispute that the donor sheep whose genetic material was used to create Dolly could not be patented, Roslin contends that copies (clones) are eligible for protection because they are “the product of human ingenuity” and “not nature’s handiwork, but [their] own.” Appellant’s Br. 17, 18. Roslin argues that such copies are either compositions of matter or manufactures within the scope of
§ 101. However, Dolly herself is an exact genetic replica of another sheep and does not possess “markedly different characteristics from any [farm animals] found in nature.” Chakrabarty, 447 U.S. at 310; see Reply Br. 13 (stating that “the clones are genetic copies”). Dolly’s genetic identity to her donor parent renders her unpatentable.

In Myriad, the Court concluded that “isolated,” naturally occurring DNA strands are not eligible for patent protection. 133 S. Ct. at 2111. Here, as in Myriad, Roslin “did not create or alter any of the genetic information” of its claimed clones, “[n]or did [Roslin] create or alter the genetic structure of [the] DNA” used to make its clones. Myriad, 133 S. Ct. at 2116. Instead, Roslin’s chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.

Related areas of Supreme Court patent case law reinforce this conclusion. For example, Supreme Court decisions regarding the preemptive force of federal patent law confirm that individuals are free to copy any unpatentable article, such as a live farm animal, so long as they do not infringe a patented method of copying. Sears Roebuck & Co. v. Stiffel Co. clarified that a state may not “prohibit the copying of [an] article itself or award damages for such copying” when that article is ineligible for patent protection. 376 U.S. 225, 232-33 (1964). In Sears, the question was whether the defendant, Sears Roebuck & Co., could be held liable under state law for copying a lamp design whose patent protection had expired. Id. at 225-26. The Court explained that “when the patent expires the monopoly created by it expires, too, and the right to make the article—including the right to make it in precisely the shape it carried when patented—passes to the public.” Id. at 230 (citing Kellogg Co. v. Nat’l Biscuit Co., 305 U.S. 111, 120-22 (1938), and Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185 (1896)). The Court further clarified that “[a]n unpatentable article, like an article on which the patent has expired, is in the public domain and may be made and sold by whoever chooses to do so.” Id. at 231; see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989). Roslin’s claimed clones are exact genetic copies of patent ineligible subject matter. Accordingly, they are not eligible for patent protection.

II

However, Roslin argues that its claimed clones are patent eligible because they are distinguishable from the donor mammals used to create them. First, Roslin contends that “environmental factors” lead to phenotypic differences that distinguish its clones from their donor mammals. A phenotype refers to all the observable characteristics of an organism, such as shape, size, color, and behavior, that result from the interaction of the organism’s genotype with its environment. A mammal’s phenotype can change constantly throughout the life of that organism not only due to en-

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2 The ’233 patent application clarifies that “[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus,” i.e., they share the same nuclear genome.
vironmental changes, but also the physiological and morphological changes associated with aging.

Roslin argues that environmental factors lead to phenotypic differences between its clones and their donor mammals that render their claimed subject matter patentable. However, these differences are unclaimed. Indeed, the word “cloned” in the pending claims connotes genetic identity, and the claims say nothing about a phenotypic difference between the claimed subject matter and the donor mammals. Moreover, Roslin acknowledges that any phenotypic differences came about or were produced “quite independently of any effort of the patentee.” Funk Bros., 333 U.S. at 131; see id. at 130 (“Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature.”); Chakrabarty, 447 U.S. at 310 (“Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”). Contrary to Roslin’s arguments, these phenotypic differences do not confer eligibility on their claimed subject matter. Any phenotypic differences between Roslin’s donor mammals and its claimed clones are the result of “environmental factors,” Appellant’s Br. 21, uninfluenced by Roslin’s efforts.

Second, Roslin urges that its clones are distinguishable from their original donor mammals because of differences in mitochondrial DNA, which originates from the donor oocyte rather than the donor nucleus. Mitochondria are the organelles (cellular bodies) that produce the energy eukaryotic cells need to function. Mitochondria possess their own DNA, which is distinct from the DNA housed in the cell’s nucleus. In the cloning process, the clone inherits its mitochondrial DNA from its donor oocyte, instead of its donor somatic cell. Therefore, Dolly’s mitochondrial DNA came from the oocyte used to create her, not her donor mammary cell. Roslin argues that this difference in mitochondrial DNA renders its product claims patent eligible.

But any difference in mitochondrial DNA between the donor and cloned mammals is, too, unclaimed. Furthermore, Roslin’s patent application does not identify how differences in mitochondrial DNA influence or could influence the characteristics of cloned mammals. As the Board found below,

[a]s for the influence of the oocyte into which the donor nucleus is transferred, the ’233 Specification teaches that “[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus, but are not strictly identical as they are derived from different oocytes. The

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3 Roslin itself explained that “[c]loned offspring may vary phenotypically due to environment.” Appellant’s Br. 3; see also id. (“[E]nvironmental factors, such as uterine environment, generate differences that prevent a clone and its parent from being phenotypically identical. *** [Therefore,] [a] clone that contains the same set of chromosomes as a single parental mammal can be distinguished from the parental mammal due to these environmental influences.”), 21 (“[E]nvironmental influences *** result in phenotypic differences.”).
significance of this different origin is not clear, but may affect commercial traits.” The Specification cautions further that “[i]t remains *** to consider whether it is possible or necessary in specific situations to consider the selection of oocytes.” Thus *** the Specification does not disclose any systematic differences in the clones that arise from the capture of the recipient oocyte.

There is nothing in the claims, or even in the specification, that suggests that the clones are distinct in any relevant way from the donor animals of which they are copies. The clones are defined in terms of the identity of their nuclear DNA to that of the donor mammals. To be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case. Here, however, the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.

Finally, Roslin argues that its clones are patent eligible because they are time-delayed versions of their donor mammals, and therefore different from their original mammals. But this distinction cannot confer patentability. As the Board noted, “[t]he difficulty with the timedelayed characteristic is that it is true of any copy of an original.” Thus, we affirm the Board’s finding that Roslin’s clones are unpatentable subject matter under § 101.